In Memory of My Mentor Pao-Lu Hsu

Academic Achievements of Professor Pao-Lu Hsu
2012 ICSA Election
Annual ICSA Banquet at JSM
Statisticians Supporting Late-stage Clinical Development at Merck
Bringing Statistical Innovation to Oncology Drug Development
Reproducible Research: Notes from the Field
Making Reproducible Research Enjoyable
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Looking Back and Looking Out

Jun Yan

The first Pao-Lu Hsu Prize, an award to be presented every three years by the ICSA, will be announced this August. The award is to “an individual under the age of 50, who makes influential and fundamental contributions to any field of statistics and probability, and exemplifies Hsu’s deep involvement in developing statistics and probability research with significant impact on education.” For the younger generation, who was Pao-Lu Hsu?

I heard Hsu’s name for the first time in early 1990s in a mathematical statistics course taught by Prof. Yaoting Zhang, who mentioned his professor, Hsu, with great passion and deep respect. It was not until about ten years later when I learned more about Hsu from a short article in “Leading Personalities in Statistical Sciences: From the Seventeenth Century to the Present”, edited by Johnson and Kotz (1997), after I started teaching. The short article made me want to know even more about him. In column “Looking Back”, we have two memorial articles about Prof. Hsu and his impact from both personal and academic perspectives. The first is by Dihe Hu, and the second by Jiading Chen and Zhongguo Zheng; all were students and colleagues of Hsu. I would suggest reading more articles collected at a website (http://www.math.pku.edu.cn/teachers/Hsu/articles.htm) in memory of Prof. Hsu, hosted by his home department, the Department of Probability and Statistics, Peking University. Interestingly, you will find that Hsu was not only a top scientist, but also versatile in traditional Chinese arts and music.

For those who are curious about how exactly statisticians play an important role in clinical and drug development, we have two articles in the “Statisticians at Work” column. Jerald Schindler and Yang Song tell about statisticians supporting late-stage clinical development at Merck. Pandurang Kulkarni, Nathan Enas, and Yanping Wang share their experience in bringing statistical innovation to oncology drug development at Eli Lilly, and illustrate what “advanced today, routine tomorrow” is, something we statisticians look out proudly. I am very happy to see more articles from our members on statisticians at work, perhaps in response to the first article in this column in the January issue. In fact, the first article in this column by Ruberg and Fu (2012) is cited here — another reason to write for the ICSA Bulletin.

Reproducible research and what it means for statisticians have gained much public attention in the news recently. In column “Blog Spot”, we republish an article on field experience in reproducible research by Roger Peng, one of the three biostatistics professors behind blog “Simply Statistics” (http://simplystatistics.tumblr.com/). In column “R ’R’ Us”, our columnist Yihui Xie tells how to make reproducible statistical research enjoyable with his R package knitr, a redesign of Sweave.

On ICSA business, we have: reports from President Ivan Chan, Executive Officer Shu-yen Ho, Treasurer Lynn Kuo, and program committee chair Tianxi Cai; biosketches of candidates of 2012 ICSA officers; highlights of the 2012 ICSA Applied Statistics Symposium from the co-chairs Mingxiu Hu and Tianxi Cai; report of winning entries of student paper awards and travel grant from Jianhua Huang and Siva Tian; report from the office ICSA; and report from the co-editors-in-chief of Statistics in Biosciences. The Joint Conference of the ICSA and the International Society for Biopharmaceutical Statistics (ISBS) is announced to be held during June 9–12, 2013, in Bethesda, Maryland.

Getting ready for the JSM 2012? Our JSM Local Chair, Ronghui (LiLy) Xu has put together a nice, detailed list of information about ICSA member meeting and annual banquet at JSM 2012, including transportation, banquet menu, additional recommended restaurants, and Chinese restaurants near the Convention Center. Websites of the restaurants are printed and also clickable if you view the electronic version with a computer or a hand-held device such as iPad/iPod or a smart phone.

Prof. Dayue Chen, Chairman of the Department of Probability and Statistics at Peking University offered tremendous help in soliciting the two memorial articles on Prof. Hsu. Contributing editor Dr. Haoda Fu organized the two articles in column “Statisticians at Work”. Contributing editor Yihui Xie kept writing articles in the “R ’R’ Us” column. My volunteer assistant Gong-yi Liao refined the mailing labels. My sincere thanks to all of them!

Enjoy the rest of the summer and see many of you in San Diego!
Dear friends and ICSA members,

Wow, summer is here with us already! As I am writing this article, I have just returned home from the ICSA Applied Statistics Symposium at Westin Waterfront Hotel in Boston. This year’s symposium featured three wonderful keynote speakers, Dr. Richard Simon from NCI, Professor Andrew Lo from MIT, and Professor Bradley Efron from Stanford University. There were multiple short courses offered on the first day, and over 100 high-quality scientific sessions over the next three days covering a wide range of topics such as financial statistics, statistics in law, statistics genetics, statistics in clinical trials and regulatory applications. The symposium was very well attended with >550 participants from academia, industry, and government. In addition, the two social events, Boston harbor cruise on Sunday evening and Conference Banquet on Monday night were all sold out. Professor Stephen Blyth from Harvard University gave an insightful speech at the banquet on the importance of statistics in financial management. Finally, the symposium was also highlighted, unexpectedly, by being in the same hotel with Mr. President Obama! Overall, I think this symposium is very successful and shows the growth and capability of our association.

The membership of ICSA has grown rapidly from just under 500 a few years ago to over 1300 currently. Last year, the constitution and by-laws were revised to reflect the current state of the society and allow further expansion of the membership, especially via sections of special interests and local chapters. I am very excited to announce that the first ever chapter of ICSA, the Canada Chapter, was born on June 23, 2012. Kudos to Professor Grace Yi of Waterloo University, who spent a lot of time and efforts in developing the governance structure and by-laws of the Canadian chapter. Many thanks also go to our Shu-yen Ho, our Executive Director, for working closely with Grace and the Executive Committee and Board of Directors in finalizing the chapter by-laws. I believe ICSA is in a strong position to support the growth of local chapters in providing membership benefits to local members.

Another piece of excellent news to share is the establishment of ICSA-Springer Book Series in May 2012. This is the first of its kind of collaboration between ICSA and a publisher to publish a series of books on different fields of statistics. We are fortunately to have Professor Jiahua Chen from University of British Columbia serve as the Editor-In-Chief of this book series. Together with the ICSA sponsored/co-sponsored journals, Statistica Sinica, Statistics in Biosciences, and Statistics and Its Interface, this book series will enhance the benefits to members and increase the influence of ICSA in the international statistical community. If you are interested in writing a book on statistics, please give the ICSA-Springer Book Series a serious consideration.

ICSA is continuing to explore ways of establishing collaborations with other societies in the future. The planning of the first joint symposium between ICSA and the International Society for Biopharmaceutical Statistics (ISBS) is well underway, with the date and venue set for June 9–12, 2013 at the Bethesda North Marriott Hotel & Conference Center, Bethesda, Maryland, USA. The 2013 ICSA International Conference, to be held from December 20–23, 2013 in Hong Kong, will be co-sponsored by the American Statistical Association (ASA), Institute of Mathematical Statistics (IMS), and International Society of Bayesian Analysis (ISBA). We also have had a discussion with ENAR about a possible collaboration and submitted an ICSA-sponsored invited session proposal for the 2013 ENAR spring meeting. In addition, ICSA is planning to host the Applied Statistics Symposium jointly with the Korean International Statistical Society (KISS) in 2014 and with the Graybill Conference in 2015.

If you are planning to attend the Joint Statistical Meetings (JSM) in San Diego (July 29 to August 2, 2012), please note that ICSA will hold the annual Members Meeting on August 1 (Wed) at 5:30 pm in San Diego Convention Center. During the Members Meeting, the 2012 election results will be announced and an award ceremony will be held for this year’s ICSA Distinguished Achievement Award and Outstanding Service Award. In addition, the first ICSA Pao-Lu Hsu Award recipients will be announced, with the official award cer-
From the ICSA Executives

Ivan S. F. Chan
2012 President, ICSA
Senior Director
Late Development Statistics
Merck Research Laboratories

From the Executive Director, ICSA

Shu-yen Ho

Dear ICSA Members,

Over the past six months, ICSA enjoyed membership growth and additional connections with other statistical institutions and organizations through co-sponsorship and co-organizing future meetings. For the membership growth, currently we have approximately 1340 active members and 40% among those are permanent members. For the connections with other organizations, please refer to our website www.icsa.org and other reports on this bulletin for more information.

The 2012 Applied Statistical Symposium was successfully held in Boston recently with over 550 participated. A report on the symposium can be found in this bulletin. It is worth noting that this symposium website was developed and maintained by the home office staff and the online registration was enhanced and streamlined to better serve symposium registrants. We plan to continue to build on this success for all future symposia and we welcome your feedback and suggestions.

The 2012 first ICSA board meeting was held on June 23, 2012 during the Applied Statistical Symposium. In that meeting, the birth of Canada Chapter was announced, the board approved ICSA 2012 awards, including the first PL Hsu award, and also approved the candidates for 2012 ICSA elections. In addition, the ICSA journals, book series, and future symposia and international conferences were also updated and all were on track and in good progress.

The annual ICSA members meeting will be held on August 1, 2012, 5:30 PM at Hilton Bayfront Hotel San Diego (room Indigo 202) during the upcoming JSM, where the 2012 awards and election results will be announced. We look forward to your participation in this members meeting. Immediately after the members meeting, ICSA welcome all members to join a banquet in a local Chinese restaurant. Details are included in this bulletin and will also be available at the ICSA table in JSM.

As always, your support of and participation in ICSA programs and activities will be important for the continued success of ICSA. Your ideas and suggestions will be greatly appreciated.

Have a great second half of the Dragon year!

Shuyen Ho, Ph.D.
ICSA Executive Director (2011-13)
Director, Statistics and Programming
GlaxoSmithKline

Reader’s Feedback: On History of ICSA

Dr. Nancy Lo, Mathematical Statistician from National Oceanic & Atmospheric Administration and former Executive Director of ICSA (1997), wrote: “It is good to see an article about early days of ICSA. F.Y.I, I wrote an article on the past, the present and the future of ICSA published in January, 1997, the 10th anniversary of ICSA. This article was also published in Encyclopedia of Statistical Science, Vol 3, John Wiley & Sons.”


We thank Dr. Lo for pointing us to this reference. The reference has been archived at [http://www.icsa.org/References/index.html](http://www.icsa.org/References/index.html). Feedbacks from readers are always welcome.
Candidates for 2012 Election of ICSA Officers

Candidates for 2013 President Elect

Lu, Ying

[PRESENT POSITION] Professor, Division of Biostatistics, Department of Health Research and Policy, Stanford University; Director, US Veterans Affairs Cooperative Studies Program Palo Alto Coordinating Center, Palo Alto, CA, USA.

[FORMER POSITION] Professor, Department of Radiology and Department of Epidemiology and Biostatistics, University of California, San Francisco, CA, USA.

[DEGREES] Ph.D. in Biostatistics (1990), University of California, Berkeley, CA, USA; M.S. in Applied Mathematics (1984), Shanghai Jiao Tong University, Shanghai, China; B.S. in Mathematics (1982), Fudan University, Shanghai, China.

[FIELDS OF MAJOR STATISTICAL ACTIVITIES] Dr. Lu’s research interests include clinical trial design, evaluation and validation of medical diagnostic tests, medical decision making, and statistical applications in osteoporosis, radiology, oncology and other disease areas.

[PUBLICATIONS] Dr. Lu has published over 210 peer-reviewed research papers in statistical and medical journals. His statistical works were published in Biometrics, Statistics in Medicine, Statistics in Biopharmaceutical Research, Medical Decision Making, Journal of Biopharmaceutical Statistics, Contemporary Clinical Trials, Statistical and Probability Letters, and Mathematics Biosciences. He also published in clinical journals, such as Journal of the American Medical Association (JAMA), Proceedings of the National Academy of Sciences (PNAS), Journal of Bone and Mineral Research, Radiology, Cancer, Osteoporosis International, and Neuroimage. He co-edited Advanced Medical Statistics with Professor Ji-Qian Fang, which was published in both English and Chinese.

[ICSA ACTIVITIES AND OFFICES HELD] Dr. Lu is a lifetime member of the ICSA. He currently serves as the Chair of the ICSA Publication Committee (2012-2013). In the past, he served as the Chair of the ICSA Program Committee from 2008-2011. He co-chaired the 2009 ICSA Applied Statistics Symposium in San Francisco, CA; chaired the short-course committee for the 2004 ICSA Applied Statistical Symposium, San Diego, CA; and organized ICSA local activities for the 2002 JSM in San Francisco.

[RELATED PROFESSIONAL ACTIVITIES] Dr. Lu is an elected fellow of the American Statistical Association. He was the recipient of the 1990 Evelyn Fix Memorial Award for excellent dissertation from the Department of Statistics, University of California, Berkeley. He also received the 2003 Healthstar Osteoporosis Medical Research Award by the Chinese Development Foundation for Science and Technology for his research accomplishment in the standardization of hip BMD, osteoporosis diagnosis, quality control and quality assurance for densitometry in major osteoporosis clinical trials, and his teaching, consulting, and promoting of osteoporosis research in China.

Dr. Lu has been actively involved in the statistical and research communities. He served as the Program Chair for the WNAR 2006 Annual Meeting. He was a member of the WNAR Regional Committee during 2007-2009, the planning and organization committee of the 1st Pacific Coast Statisticians and Pharmacometricians Innovation Conference (PaSiPHIC), and the scientific program committees for many statistical and clinical conferences and symposiums. Dr. Lu has served as a reviewer and study section member for NIH grant applications since 2001; a member of the FDA Advisory Panel on Peripheral CNS Diseases from 2007-2011; a member of the American Joint Committee on Cancer (AJCC) Statistical Task Force on 9th Edition of AJCC Tumor Staging from 2006-2009, and the AJCC Molecular Modeler Group since 2007. He also served as the only statistical member in the International Committee for Standardization in Bone Measurement (1995-2000) and the Committee on Standards in Bone Measurements of the International Society of Clinical Densitometry (2005). He is a member of the external advisory board of Tufts Medical Center – Cancer Center, the external advisory board of the UCLA Neuro-Oncology SPORE program, and the international advisory board of Shanghai Jiao Tong University School of Bioengineering. In addition, Dr. Lu continuously served as an ASA San Francisco Chap-
The success of an organization depends on its vibrant members. Under the leadership of past presidents, ICSA has grown into an association of 1,000 members. It is both an exciting challenge and an opportunity to continue to foster the growth of the association. We can attract the most talented statisticians not only through our professional services but also by encouraging members to have ownership of the association through their initiatives and activities. I would like to work with membership committee to expand sections and chapters so members can cultivate their specific regional interests and objectives. In addition, we want to expand our membership to areas such as Mainland China and Europe. We can host international webinars to provide cutting edge continuing education courses to potential new members as outreach to statisticians in those areas. We also want to take full advantage of social media web tools, such as Google+ to hold large multi-person video meetings; LinkedIn to establish a professional presence and increase prominence by having our members list ICSA in their profiles; or other social medium that could provide free recruitment and promotion for the association.

Our organization would not be able to function without the generosity of hard working volunteers, officers, and directors who devote their time and effort to enable the ICSA thrive. Many excellent ideas and best practices have been developed over the years by our volunteers. If I am elected, I will work with committees and volunteers to establish operational manuals, document the best practice, and develop tools for the betterment of the ICSA. I will also work with the ICSA Board of Director to improve ICSA infrastructure to ensure that our volunteers get the help they need and reduce the burden from administrative tasks, thus allowing members to focus their energy on creative activities and promoting statistical sciences.

Compared to other well-established statistical associations, ICSA is unique in its truly international representation. It is an organization made up of individuals of all race, creed, color, sex, and nationality. Its membership comes from all over the world. In the past, ICSA has had bi-annual international conferences in Asia and annual applied statistical symposium in the North America that bridges international exchanges. However, our recent past efforts have been focused on scholarly activities. The ASA has demonstrated the benefits of promoting better understanding and interest in statistics in the general public through its K-12 statistical education program. The ICSA is in a privileged position to exercise its influence on K-12 statistical education in Asia. These and other similar initiatives can help our passionate members inspire the next generations of statisticians. I hope to channel all the incredible talents of this association to make a positive impact in the world.

ICSA is 25 years old this year. This is a beautiful age - full of energy and imagination. I am certainly looking forward to working with our organization regardless of the election results. Let’s work together to make ICSA the most successful organization.

Shen, Wei

[PRESENT POSITION] Senior Director, Global Statistics and Advanced Analytics, Eli Lilly and Company.


[FIELDS OF MAJOR STATISTICAL ACTIVITIES] Dr. Shen’s research interests include statistical methods and application in clinical trials, Bayesian and empirical Bayes methods, joint modeling of...
longitudinal and time-to-event data, survival analysis, non-parametric methods, and health outcomes research.


[ICSA ACTIVITIES AND OFFICES HELD] Dr. Shen is a life member of ICSA. He currently serves as a member of the ICSA nomination committee. Dr. Shen was elected to the ICSA board in 2007, and he served on the ICSA Board of Directors from 2008 to 2010. Dr. Shen co-chaired the 2010 ICSA Applied Statistics Symposium in Indianapolis. He has served on various ICSA committees, including ICSA local event committee (2000), membership committee (2004 â˘A¸ S 2007), committee of promoting academic-industrial collaboration (2009-2010), and nomination committee (2012). Dr Shen has been involved in organizing invited sessions at ICSA Applied Statistics Symposium and ICSA International Conference.

[RELATED PROFESSIONAL ACTIVITIES] Dr. Shen is an elected member of the International Society for Biopharmaceutical Statistics (ISBS) Conference Program Committee. He has served on the scientific program committee for the 1st and 2nd ISBS international conferences in Shanghai (2008) and Berlin (2010). Currently, he serves on the scientific program committee for the 2nd Joint Bio-statistics Symposium in Beijing (2012) and the joint ISBS/ICSA statistics symposium in Washington DC (2013). Dr Shen has organized and chaired sessions at major statistical conferences, including the Joint Statistical Meetings, FDA/Industry Statistics Workshop, and ISBS international conferences. Dr. Shen has served as a reviewer for several journals, including Biometrics, Statistics in Medicine, The American Statistician, Computational statistics and data analysis, Journal of Biopharmaceutical Statistics, Quality of Life Research, Medical Care, and Journal of clinical epidemiology.

[STATEMENT] It is a great honour to be nominated as a candidate for the president of ICSA. I’d like to thank Ivan Chan (ICSA president) and Sue-Jane Wang (Chair of the ICSA nomination committee) for their encouragement and support.

My first involvement with ICSA came in 2000, when the joint statistical meetings (JSM) were held in Indianapolis and I served as a member of the local event committee. Over the years I was fortunate to serve ICSA and its members in various ways, including sitting on the ICSA board of directors (2008 to 2010), participating in various ICSA committees, and co-chairing the 2010 ICSA applied statistical symposium in Indianapolis.

With its outstanding leadership and highly engaged members, ICSA has become one of the premier statistical organizations in the world. As a lifetime member of ICSA, I am very excited to witness and be a part of the growth of ICSA. I have seen where we have been, and I am passionate about the opportunity to lead ICSA to reach the next level.

If elected, I plan to focus on the following areas to make ICSA a stronger and more influential organization:

1) Grow the influence of ICSA through expanded collaborations. In this age of information explosion and social networking, growth will come through effective collaborations. Over the years, ICSA has developed strong partnerships with several sister organizations, including the American Statistical Association. I will continue these efforts to expand our partnerships with a broad range of organizations, particularly in the area of membership drive and sponsorship of conferences. While serving on the ICSA committee of “promoting academic-industrial collaboration” (2009 to 2010), I have worked closely with ICSA past-president Xuming He to introduce ways of productive collaborations between academic and industrial statisticians. As our membership from industry continues to rise, I will support initiatives to strengthen collaborations among industry, academia, and government by leveraging information and networking. Finally, collaborations should not be limited by where we are located. ICSA, as an international statistical organization, has the responsibility to lead collaborations across the globe. Given most of our members are US-educated with Chinese-origin, we have a unique opportunity to bridge the knowledge gap between US and China/Asia. As the demand of statistical talents continues to explode, future talents are expected to increasingly come from China/Asia. Through our rich
network and educational programs, ICSA is positioned to raise the supply and prominence of next-generation of statisticians in China/Asia to meet the global growth of statistical applications. I will lead ICSA to increase our efforts in scientific collaborations, educational programs, and outreach efforts in China, Asia, and Europe.

2) Transform ICSA through scientific leadership and operational excellence. ICSA has already established its scientific leadership in the statistical discipline through its flagship journal Statistica Sinica, and its annual applied statistical symposium. I will lead ICSA to strengthen our scientific leadership position, by propelling Statistica Sinica into a top-tier journal in the international statistics community, and making our newly established journal Statistics in BioSciences one of the fast growing journals in the field of applied statistics. Given the growing importance of statistical applications outside of North America, I will work with the program committee to increase of the frequency of ICSA international conferences and possibly add regional conferences. Our leadership not only lies in our scientific work, but also in the quality and skills of our members. After all, our members are our most important assets. With so many young talents joining ICSA every year, we owe our members a huge responsibility of career growth and leadership development. ASA, under its current president, Robert Rodriguez, has launched a series of effort to improve the leadership skills of its members. For members of ICSA, we must provide opportunities for growth and character building: I will create a task force focusing on mentoring and leadership development. I will advocate inclusion of leadership development in our publications and conferences, to enable our members to become successful scientists and leaders in the 21st century.

Last but not least, with our fast growing membership and size of our conferences, our operational burden continues to increase. Thanks to past ICSA executive director and president-elect Minghui Chen, the Office of ICSA started its operation in 2007. In order for ICSA to function well as a premier professional organization, we are at a tipping point to establish a right operational structure so that ICSA can sustain its growth in the next decade. I will lead efforts to expand ICSA office by adding permanent and professional staff. This is not to diminish the support of our volunteers. Indeed, our operational excellence will allow us to deliver better services to our members and enable our volunteers to focus on strategic and scientific leadership of our association. By providing a strong operational framework, our scientific leadership may grow through the spark of innovative thinking and collaboration.

Thank you for giving me the opportunity to share my ideas and passion about the future of ICSA. I am excited and committed to the mission of ICSA. Inspired by many dedicated ICSA members and leaders, I am humbled by this opportunity to serve ICSA as its president. I ask for your support and invite you to join me in our journey to take ICSA to the next level together.

Candidates for 2013 Biometrics Section Chair

Liu, Aiyi

[PRESENT POSITION] Senior Investigator, Biostatistics and Bioinformatics Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.

[FORMER POSITION] Investigator, Biostatistics and Bioinformatics Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health; Assistant Professor, Department of Biostatistics, Georgetown University Medical Center.

[FIELDS OF MAJOR STATISTICAL ACTIVITIES] Research interests include general statistical theory and methods, sequential and adaptive methods in clinical trials and biomedical research, statistical methodology for diagnostic biomarkers, semiparametric and nonparametric methods for multidimensional data, genome-wide association studies, and group testing methodology.

[SELECTED PUBLICATIONS] Author of about 100 publications including 66 peer-reviewed papers in statistical journals including Biometrics, Biometrika, Biostatistics, Statistica Sinica, and Statistics in Medicine.

[ICSA ACTIVITIES] Permanent member of ICSA; Member, Planning Committee, ICSA 2005 Applied Statistics Symposium; Session organizer and chair on “Pooling Biospecimens: Methodologies, Applications and Limitations”. ICSA Applied Statistics Symposium, 2005; Session organizer and chair on “Sequential Methods for Evaluation of Diagnostic Biomarkers”. ICSA Applied Statistics Symposium, 2006; Member, Board of Directors, ICSA, 2007-2009; Session organizer on “Dealing with Measure-


Liu, Guanghan (Frank)

[PRESENT POSITION] Director, Clinical Biostatistics, Merck Research Laboratories, North Wales, PA.


[DEGREES] Ph.D in Statistics, University of California, Los Angeles, CA, 1993; M.S. in Mathematics, University of California, Los Angeles, CA, 1990; M.S. in Statistics, East China Normal University, China, 1987; B.S. in Mathematics, East China Normal University, China, 1894.

[FILED OF MAJOR STATISTICAL ACTIVITIES] Research in clinical trial design and data analysis including longitudinal data analysis; missing data methodology; analysis of survival data; Bayesian methods in clinical trials specifically in assessing probability of success and in handling missing data.


[ICSA ACTIVITIES] Permanent Member of ICSA; Served as Board of Director (2007-2009), Member of Publication Committee (2012), Member of organizing committee for the ICSA Applied Statistics Symposium (2008) and Special Issue Editorial Board for publishing special issues at Statistics in Biopharmaceutical Research (2009).

[RELATED PROFESSIONAL ACTIVITIES] Active member of ASA and ENAR, organizing and/or chair sections and making presentations; Co-chair DIA scientific working group on Bayesian methods for missing data handling; Referee for statistical journals including Biometrics, Statistics in Medicine, Journal of Biopharmaceutical Statistics, Pharmaceutical Statistics, Statistics in Biopharmaceutical Research, and The American Statistician.


Zhang, Zhengjun

[PRESENT POSITION] Associate Professor, Department of Statistics, University of Wisconsin-Madison.


[FIELD OF MAJOR STATISTICAL ACTIVITIES] Statistics of extremes with application to finance, insurance and environmental sciences; time series; risk management; medical statistics, etc.


[ICSA ACTIVITIES] ICSA student paper award and travel fellowship, 2002; Organizer of invited talk sessions for ICSA applied statistics symposium; Lifetime member of ICSA.

[RELATED PROFESSIONAL ACTIVITIES] Associate Editor of Journal of Business and Economic Statistics starting 2012, and Associate Editor of...
Zhang, Wei

[PRESENT POSITION] Regional Head of Biometrics and Data Management, Asia/MENA, Boehringer Ingelheim.

[FORMER POSITION] Senior Principal Biostatistician, Boehringer Ingelheim

[FILED OF MAJOR STATISTICAL ACTIVITIES] Research interests include adaptive designs, non-inferiority trials, doubly censored data, and survival analysis.

[SELECTED PUBLICATIONS] Published more than a dozen of papers in statistical and medical journals.

[ICSA ACTIVITIES] Member of ICSA; Member of Executive Committee for ICSA 2011 Applied Statistics Symposium

[WANG, MING-DAUH]


[FILED OF MAJOR STATISTICAL ACTIVITIES] Research and application of statistics in pharmaceutical setting; interests include clinical trials, Bayesian inference, adaptive design, biomarker inference.

[SELECTED PUBLICATIONS] Published papers in statistical and medical journals, including Statistics in Medicine, Biometrical Journal, and Journal of the American Medical Association.

[ICSA ACTIVITIES] Member of ICSA; Treasurer of 2010 ICSA Applied Statistical Conference.

[STATEMENT] Having long benefited from the service of ICSA and started to give back, I am feeling the desire and burden to serve more as a Board member. If elected, I will strive along with other Board members to bring about fuller realization of ICSA objectives.

Ji, Yuan

[PRESENT POSITION] Director of Cancer Informatics, Center for Clinical and Research Informatics, NorthShore University HealthSystem.

[FORMER POSITION] Associate Professor, Department of Biostatistics, The University of Texas M.D. Anderson Cancer Center.

[FILED OF MAJOR STATISTICAL ACTIVITIES] Research interests include Bayesian Inference, genomics (next-generation sequencing and other high throughput biotechnology), integromics, network models, and adaptive designs for clinical trials.

[SELECTED PUBLICATIONS] Over 50 papers and manuscripts ranging across a variety of journals, including JASA, Biometrics, Bioinformatics, JNCI, Lancet Oncology, Clinical Trials, Statistics in Medicine, and Statistica Sinica.

Wang, Ming-Dauh

[PRESENT POSITION] Regional Head of Bioinformatics and Data Management, Asia/MENA, Boehringer Ingelheim.

[FORMER POSITION] Senior Principal Biostatistician, Boehringer Ingelheim

[FILED OF MAJOR STATISTICAL ACTIVITIES] Research interests include adaptive designs, non-inferiority trials, doubly censored data, and survival analysis.

[SELECTED PUBLICATIONS] Published more than a dozen of papers in statistical and medical journals.

[ICSA ACTIVITIES] Member of ICSA; Member of Executive Committee for ICSA 2011 Applied Statistics Symposium

[WANG, MING-DAUH]


[FILED OF MAJOR STATISTICAL ACTIVITIES] Research and application of statistics in pharmaceutical setting; interests include clinical trials, Bayesian inference, adaptive design, biomarker inference.

[SELECTED PUBLICATIONS] Published papers in statistical and medical journals, including Statistics in Medicine, Biometrical Journal, and Journal of the American Medical Association.

[ICSA ACTIVITIES] Member of ICSA; Treasurer of 2010 ICSA Applied Statistical Conference.

[STATEMENT] Having long benefited from the service of ICSA and started to give back, I am feeling the desire and burden to serve more as a Board member. If elected, I will strive along with other Board members to bring about fuller realization of ICSA objectives.

Fu, Haoda

[PRESENT POSITION] Senior Research Scientist, Group Leader, Global Statistics, Eli Lilly and Company


[FILED OF MAJOR STATISTICAL ACTIVITIES] Dr. Fu’s research interests include developing and applying Bayesian methods in pharmaceutical research. He published 21 manuscripts and covers areas in: Bayesian adaptive design, indirect and mixed treatment comparison, copula methods for joint modeling with applications in oncology and diabetes areas, Bayesian decision rule for drug development go/no-go decision, and Bayesian method for drug safety evaluation.

[RELATED PROFESSIONAL SERVICES AND ACTIVITIES] Dr. Fu is actively involved in professional activities. He is a member of ICSA,
ENAR and ASA. He was selected as ENAR Regional Advisor Board member in 2009 and currently serves the ICSA membership committee. Dr. Fu chaired numerous invited and contributed sessions in ENAR, JSM, and MBSW (Midwest Biopharmaceutical Statistics Workshop) conferences. He also served as reviewers for multiple statistical and medical journals, including statistics in medicine, journal of biopharmaceutical statistics etc.

[STATEMENT] It is my great honor to be nominated as a candidate for the director of ICSA. Thank the Nomination and Election Committee for this opportunity. During the past 5 years, I was so grateful to have the chance to closely work with many talented statisticians in Lilly, including Wei Shen and Yongming Qu who are very active in our ICSA communities. I was also very glad to have many external collaborations. Through these collaborations, I feel that there is a need to improve the connection between pharmaceutical research and current methodology research in academia. Although there are many statisticians working in industry, they may not be well represented in different statistician associations. I hope that my involvement can continue our ICSA tradition to bring diversified opinions, also to promote our ICSA in industry.

Lo Huang, Mong-Na

[PRESENT POSITION] Professor, Department of Applied Mathematics, National Sun Yat-sen University, Kaohsiung, Taiwan.


[FIELDS of MAJOR STATISTICAL ACTIVITIES] Research interests include Experimental designs, Industrial statistics, Environmental statistics.

[SELECTED PUBLICATIONS] Published 51 papers in statistical journals including Biometrika, Environmetrics, Metrika, Sankhya, Statistica Sinica, Statistics in Medicine, Journal of Multivariate Analysis, Journal of Statistical Planning and Inference, Computational Statistics and Data Analysis.

[RELATED PROFESSIONAL SERVICES AND ACTIVITIES] Associate Editor for Statistica Sinica, Metrika, Journal of the Chinese Statistical Association, Executive Managing Editor for Journal of Data Science, Member of the Board of Review Committee of National Science Council, Taiwan. Member of the Council Committee of National Science Council, Taiwan. Committee Member of the Board of the Chinese Institute of Probability and Statistics of Supervisors.

Tseng, George C.

[PRESENT POSITION] Associate Professor, Department of Biostatistics, University of Pittsburgh (Primary appointment). Associate Professor, Department of Human Genetics, University of Pittsburgh (Secondary appointment). Associate Professor, Department of Computational and Systems Biology, University of Pittsburgh (Secondary appointment).

[FIELDS of MAJOR STATISTICAL ACTIVITIES] Research interests include statistical methodology and inference of high-throughput genomic data analysis, genomic meta-analysis, genomic integrative analysis, machine learning and clustering analysis.


Lu, Wenbin

[PRESENT POSITION] Associate Professor, Department of Statistics, North Carolina State University

[FORMER POSITION] Assistant Professor, Department of Statistics, North Carolina State University

[FIELDS of MAJOR STATISTICAL ACTIVITIES] Research interests include statistical methods for clinical trials and personalized medicine, survival analysis, nonparametric/semi-parametric inference, model and variable selection methods and statistical genetics.
[SELECTED PUBLICATIONS] Published 34 papers in statistical journals including Biometrika, JASA, Statistica Sinica, Biometrics, Biostatistics and Lifetime Data Analysis.


Chang, Yuan-Chin Ivan

[PRESENT POSITION] Research Fellow, Institute of Statistical Science, Academia Sinica, Taipei, Taiwan.

[FORMER POSITION] National Chengchi University, Taipei, Taiwan; Associate Research Fellow, Institute of Statistical Science, Academia Sinica, Taipei, Taiwan; Deputy Director, Institute of Statistical Science, Academia Sinica, Taipei, Taiwan; Supervisor, Statistical Computing Lab, Institute of Statistical Science, Academia Sinica, Taipei, Taiwan.

[FIELD OF MAJOR STATISTICAL ACTIVITIES] Research interests include Sequential Analysis and Its Applications, Generalized linear models and Classification.


[RELATED PROFESSIONAL ACTIVITIES] Administration Services: International Association of Statistical Computing Asian Regional Section Board Member (ISAC-ARS BoD, since 2009); Member of Legal Affairs Committee, Ministry of Examination, Examination Yuan of ROC (2009); Advisory Committee: Academia Sinica Computing Center (2005 - 2006); Committee of Art and Culture Activity: Academia Sinica (2000 - 2007); Supervisor of Computing Lab., Inst. of Statistical Science, Academia Sinica.


Shi, Jian Qing


[FIELD OF MAJOR STATISTICAL ACTIVITIES] Nonparametric functional data analysis, Incomplete data and model uncertainty with applications in medicine, Covariance structural analysis and latent variable models, Statistical diagnostics.

[SELECTED PUBLICATIONS] Dr. Shi has published over 40 refereed papers in major statistical journals, including JRSSB, Biometrika, Biometrics and Statistica Sinica.

[ICSA ACTIVITIES] Member of ICSA.

ICSAS Member Meeting and Annual Banquet at JSM 2012

Ronghui (Lily) Xu

2012 JSM will take place on July 28 — August 2 at the San Diego Convention Center, California. ICSA member meeting and the annual banquet are scheduled on Wednesday, August 1st. The banquet will be held at Jasmine Chinese Seafood Restaurant, 7:00pm — 10:00pm, 4609 Convoy St. #A, San Diego, CA 92111, (858) 268-0888, http://www.jasmineseafood.com/jsr/html/home.html.

Transportation Transportation will be arranged after the member meeting at the Convention Center. Banquet tickets and price (including transportation) will be available at the ICSA Conference Booth.

Banquet menu
1. Peking Duck
2. Sauteed Chicken & Shrimp with Pine Nuts
3. Sauteed Seafood in Phoenix Nest
4. Supreme Seafood Soup with Bean Curd
5. Lobster with Ginger and Scallions
6. Braised Garden Greens with Mushrooms
7. Peking Pork Chops
8. Twin Flavored Rock Cod Fillet
9. House Special Fried Rice
10. Dessert of the Day

Additional Recommended Restaurants Convoy Street (where the banquet takes place) is where Asian businesses concentrate in San Diego. Here are some additional recommended restaurants, all are Chinese except otherwise specified (some are small and popular on the weekends, so you might want to call first):
• Emerald Restaurant, 3709 Convoy St., San Diego, CA 92111, (858) 565-6888, http://emeraldr estaurant.com/
• China Max, 4698 Convoy St. #101, San Diego, CA 92111, (858) 650-3333, http://www.chinamaxsandiego.com/
• Spice City, 4690 Convoy St., San Diego, CA 92111, (858) 278-1818, http://spicycity.menutoeat.com/
• Tofu House [Korean], 4646 Convoy St., San Diego, CA 92111, (858) 576-6433, http://convoytofuhouse.menutoeat.com/
• Pho T Cali [Vietnamese, near Convoy], 7351 Clairemont Mesa Blvd., San Diego, CA 92111, (858) 565-6997, http://www.photcalisd.com/
• Great Plaza Buffet (if you are in the Pacific Beach area), 1840 Garnet Avenue, San Diego, CA 92109, (858) 273-6868, http://greatplazabuffet.com/

Chinese Restaurants Near the Convention Center Chinese restaurants near the convention center in downtown San Diego (also called the Gaslamp area) can be found at: http://www.yelp.com/search?find_desc=chinese+food+downtown+gaslamp&find_loc=San+Diego%2C+CA

Ronghui (Lily) Xu, Ph.D.
JSM Local Chair, ICSA
Professor
Division of Biostatistics and Bioinformatics
Department of Family and Preventive Medicine and Department of Mathematics
Director, CTRI Design, Biostatistics and Ethics
University of California, San Diego
9500 Gilman Drive, Mail Code 0112
La Jolla, CA 92093-0112
Phone: 858-534-6380
Fax: 858-534-5273
Email: rxu@ucsd.edu
# International Chinese Statistical Association
## Profit and Loss
### Jan 1, 2012 through June 30, 2012

<table>
<thead>
<tr>
<th>Balance, Dec 31, 2011</th>
<th>$133,632.12</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Income</strong></td>
<td></td>
</tr>
<tr>
<td>Advertising Fee</td>
<td>$100.00</td>
</tr>
<tr>
<td>Membership fee</td>
<td>$8,860.00</td>
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<tr>
<td><strong>Total Income</strong></td>
<td>$8,960.00</td>
</tr>
<tr>
<td><strong>Expense</strong></td>
<td></td>
</tr>
<tr>
<td>Miscellaneous</td>
<td></td>
</tr>
<tr>
<td>IMS Bulletin, two ½ page ads for Pao-Lu Hsu Award</td>
<td>$540.00</td>
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<tr>
<td>Paypal Service charge</td>
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<tr>
<td>Accountant (2011 Tax Form)</td>
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<tr>
<td>Five Star Tours (JSM Banquet Bus)</td>
<td>$1,392.00</td>
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<td><strong>Total Miscellaneous</strong></td>
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<tr>
<td>Statistica Sinica (20-4, 21-1, 21-2, 21-3, &amp; 21-4)</td>
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<td>Printing and Reproduction</td>
<td></td>
</tr>
<tr>
<td>January ICSA Bulletin</td>
<td>$3,669.00</td>
</tr>
<tr>
<td><strong>Total Postage, Printing, and Reproduction</strong></td>
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<td><strong>Total Expense</strong></td>
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<tr>
<td>Interest income from CD</td>
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<tr>
<td><strong>Net Income</strong></td>
<td>$-1,048.31</td>
</tr>
</tbody>
</table>
# International Chinese Statistical Association

## Balance Sheet

Jan 1, 2012 through June 30, 2012

### ASSETS

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checking/Savings</td>
<td></td>
</tr>
<tr>
<td>Checking</td>
<td>$80,847.51</td>
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<tr>
<td>CD</td>
<td>$51,736.30</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td><strong>$132,583.81</strong></td>
</tr>
</tbody>
</table>

### LIABILITIES & EQUITY

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity</td>
<td></td>
</tr>
<tr>
<td>Opening Balance Jan 1, 2012 of ICSA</td>
<td>$133,632.12</td>
</tr>
<tr>
<td>Jan – Jun 2012 Net Income</td>
<td>-$1,048.31</td>
</tr>
<tr>
<td><strong>Total Equity</strong></td>
<td><strong>$132,583.81</strong></td>
</tr>
</tbody>
</table>

**TOTAL LIABILITIES & EQUITY**

**$132,583.81**

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## Report from the Program Committee

*Tianxi Cai*

### ICSA Program Committee

1. The ICSA is collaborating the Eastern North American Region (ENAR) of the International Biometrics society to have one invited session at the 2013 ENAR annual conference dedicated as a special session organized by the ICSA. This year, the invited session proposal will be submitted as a session on the ICSA sponsored journal, SIB.

2. The program committee is working with the 2014 applied symposium chair Dongseok Choi to initiate discussions on preparing for the symposium and exploring the possibility of letting Korean International Statistical Society to co-sponsor the symposium.

3. The ICSA Canadian chapter has been formally founded on June 23nd, 2012. Professor Grace Yi from the University of Waterloo will serve as the founding president of the new chapter.

### Past events in 2012

1. The ICSA co-sponsored the 19th IMS/ASA Spring Research Conference (SRC) on Statistics in Industry and Technology: Enabling the Interface between Statistics and Engineering, which took place successfully at Harvard University on June 12–15, 2012. The goal of the conference was to promote interdisciplinary research in statistical methods in engineering, science and technology and to stimulate interactions among statisticians, researchers in the application areas, and industrial practitioners.

2. ICSA 2012 Applied Statistical Symposium was held successfully in Westin Waterfront, Boston, Massachusetts between June 23 to June 26, 2012. Detailed information on this
3. JSM will take place in August at San Diego, California. There will be an ICSA member meeting from 5:30 PM to 7:00 PM on August 1st and a banquet following the meeting at the Jasmine Seafood Restaurant. Professor Ronghui (Lily) Xu, UCSD Biostatistics is the Chair for the local committee. Please contact her at rxu@math.ucsd.edu if you have any additional suggestions/comments.

Year 2013

1. ICSA 2013 Applied Statistical Symposium will be held in Bethesda, MD. Drs. Yi Tsong (yi.tsong@fda.hhs.gov) and Aiyi Liu (liua@mail.nih.gov) are the Chairs of the ICSA organization committee. The ICSA Board has approved a proposal by the organization committee to join the 2013 symposium with the International Conference of the International Society for Biopharmaceutical Statistics (ISBS). Details of this event will be forthcoming.

2. The 2013 (Ninth) ICSA International Conference will be held December 20–23, 2013 at Lam Woo International Conference Centre, Hong Kong Baptist University. For more information, please contact Professor Lixing Zhu (lzhu@hkbu.edu.hk) at Hong Kong Baptist University. Details will be developed and announced.

Year 2014

1. ICSA 2014 Applied Statistical Symposium will be held in Portland, Oregon. If you would like to help, please contact Dr. Dongseok Choi (choid@ohsu.edu).

Year 2015

1. ICSA 2015 Applied Statistical Symposium will be held in Fort Collins, Colorado. If you would like to help, please contact Dr. Naitee Ting (Naitee.Ting@boehringer-ingelheim.com) or Professor Haonana Wang (wanghn@stat.colostate.edu).

If you would like to have ICSA co-sponsorship for statistical conferences and meetings, please use the website http://www.icsa.org/meetings/co-sponsorship/index.html to submit your application for co-sponsorship.

The program committee would appreciate comments and suggestions to improve ICSA programs. Please send your inputs to Professor Tianxi Cai (tcai@hsph.harvard.edu).

Tianxi Cai, Ph.D.,
Chair, ICSA Program Committee (2012–2013)
Associate Professor of Biostatistics
Department of Biostatistics
Harvard University

Highlights of 2012 ICSA Applied Statistics Symposium

Mingxiu Hu and Tianxi Cai

The 21st ICSA Applied Statistics Symposium was successfully held from June 23 to June 26, 2012, in the Westin Boston Waterfront Hotel, located in the beautiful seaport district of Boston, Massachusetts. International Society for Biopharmaceutical Statistics (ISBS) and American Statistical Association (ASA) co-sponsored the conference. There were 552 conference participants, 140 short course attendees, and 18 student volunteers from Harvard University, Brown University, University of New Hampshire, and University of Chicago. Over 400 papers were presented in 103 scientific sessions. The two social events, the Boston Harbor Sunset Cruise and the Banquet, were both sold out with 200 and 250 participants, respectively. We would like to apologize to those who wanted to participate in these events but could not due to the limitation of capacity.

Three keynote speeches were delivered by world renowned speakers. Dr. Richard Simon of National Cancer Institute presented “On the Road to Personalized Genomic Medicine in Oncology,” Professor Andrew Lo of MIT discussed “Big Data, Systemic Risk, and Financial Crises,” and
Professor Bradley Efron of Stanford University presented “Model Selection, Estimation, and Bootstrap Smoothing.” In addition, Dr. Steve Blyth of Harvard University delivered the banquet speech.

All seven short courses were well attended with an average of 20 attendees per course. The five half-day short courses were: “Regulatory Experiences versus Consulting Experiences in Planning and Implementing Adaptive Clinical Trials” by Drs. Sue-Jane Wang of FDA and Cyrus Mehta of Cytel, “Causal Inference from Observational and Randomized Studies with Treatments that Vary over Time” by Drs. James Robins and Eric Tchetgen of Harvard University, “Analysis of Biomarkers for Prognosis and Response Prediction” by Dr. Patrick Heagerty of University of Washington, “Statistical Machine Learning in Modern Data Analysis” by Dr. Hao Helen Zhang of North Carolina State University, and “Comparative Effectiveness Research: Introduction for Statisticians” by Drs. Constantine Gatsonis of Brown University and Sharon-Lise Normand of Harvard University.

The two full-day short courses were: “Hybrid Bayesian Adaptive Clinical Trial Designs” by Dr. Peter Thall of MD Anderson Cancer Research Center, and “Analysis of Genome-Wide Sequencing Association Studies” by Drs. Xihong Lin of Harvard University and Yun Li of University of North Carolina at Chapel Hill.

This year we increased the number of Student Travel Awards from 3 to 4 in addition to J.-P. Hsu Pharmaceutical and Regulatory Science Student Paper Award. The winners of this year’s competition were Yingqi Zhao from University of North Carolina at Chapel Hill (J.-P. Hsu Student Paper Award), Peisong Han from University of Michigan, Xueying Chen from Rutgers University, Sy Han Chiou from University of Connecticut, and Olivia Yueh-Wen Liao from Stanford University. We are
thankful to the Student Award Committee for hosting this competition and for selecting these excellent student papers.

The symposium received financial support from 17 organizations: Millennium/The Takeda Oncology Company, the International Society for Biopharmaceutical Statistics (ISBS), American Statistical Association, Abbott, Amgen, Boehringer Ingelheim, BrighTech, Celgene, Cytel, Genentech, Pfizer, Novartis, Vertex, Eli Lilly, Mitsubishi Tanabe Pharma, Bristol-Myers Squibb, and Sanofi Aventis. We are sincerely grateful to these organizations for their generous support and to the Fund-raising Committee for their successful efforts.

The committee is considering a proposal by Springer to publish the first proceeding of the ICSA Applied Statistics Symposium. If you are interested in publishing your papers in the proceeding or have any questions, please contact us.

We would like to extend our genuine gratitude to all the volunteers, speakers, meeting participants, sponsors, and exhibitors. It is all because of you that this symposium becomes successful. We are especially grateful to the organizing committee members and many other volunteers for contributing numerous hours in preparing the conference, and to the programming committee members and session organizers for assembling the keynote speeches, the short courses, and the 103 scientific sessions.

Hope you enjoyed the conference and your visit to Boston! To share a few fine moments, several pictures taken by Hongliang Shi are presented in this issue of the ICSA Bulletin.

Mingxiu Hu, Ph.D.
Co-Chair, ICSA 2012 Applied Statistics Symposium
Head of Biostatistics & Statistical Programming
Millennium: The Takeda Oncology Company

Tianxi Cai, Ph.D.,
Co-Chair, ICSA 2012 Applied Statistics Symposium
Associate Professor of Biostatistics
Department of Biostatistics
Harvard University
Recipients of Student Paper Awards and Travel Grants

Jianhua Huang and Siva Tian

The student travel award committee met on April 18th, 2012. The committee received 20 submissions for this year’s competition. All papers are of high quality and worthy of consideration for an award. It was difficult for the committee to make the decision. After careful considerations, the committee selected five papers for an award because they contain extraordinary innovations and they together cover different applied areas. Each awardee received $400 cash award after the conference registration and free registration for one short course. All awardees were invited to present their papers at the 2012 ICSA Applied Statistics Symposium.

The committee selected the paper

• “Estimating Individualized treatment rules using outcome weighted learning” by Yingqi Zhao (University of North Carolina, Advisors: Donglin Zeng and Michael Kosorok)

for the Jiann-Ping Hsu Pharmaceutical and Regulatory Sciences Student Paper Award.

The other four papers selected for a travel award are:

• “Efficient Estimation For Missing Outcome Data With Surrogate Using Conditional Empirical Likelihood” by Peisong Han (University of Michigan, Advisors: Lu Wang and Peter X.-K. Song)

• “Biomarker-Based Adaptive Accrual Designs for Confirmatory Oncology Trials” by Olivia Yueh-Wen Liao (Stanford University, Advisor: Tze-Leung Lai)

• “Semiparametric Multivariate Accelerated Failure Time Model with Generalized Estimating Equations” by Sy Han Chiou (University of Connecticut, Advisor: Jun Yan)

• “A Split-and-Conquer Approach for Analysis of Extraordinarily Large Data” by Xueying Chen (Rutgers University, Advisor: Minge Xie)

We would like to take this opportunity of thank all the committee members:

• Jianhua Huang (Texas A&M University) Chair

• Siva Tian (University of Houston) Co-chair

• Xuelin Huang (MD Anderson Cancer Center)

• Hao Liu (Baylor College of Medicine)

• Peng Wei (UT Health Science Center)

The abstract of the winning papers are as follows.

Authors: Yingqi Zhao, Donglin Zeng, A. John Rush, Michael R Kosorok
Title: Estimating Individualized treatment rules using outcome weighted learning
Abstract: There is increasing interest in discovering individualized treatment rules for patients who have heterogeneous responses to treatment. In particular, one aims to find an optimal individualized treatment rule, which is a deterministic function of patient specific characteristics maximizing expected clinical outcome. In this paper, we first show that estimating such an optimal treatment rule is equivalent to a classification problem where each subject is weighted proportional to his or her clinical outcome. We then propose an outcome weighted learning approach based on the support vector machine framework. We show that the resulting estimator of the treatment rule is consistent. We further obtain a finite sample bound for the difference between the expected outcome using the estimated individualized treatment rule and that of the optimal treatment rule. The performance of the proposed approach is demonstrated via simulation studies and an analysis of chronic depression data.

Authors: Peisong Han, Lu Wang, Peter X.-K. Song
Title: Efficient Estimation For Missing Outcome Data With Surrogate Using Conditional Empirical Likelihood
Abstract: We consider parametric regression where the outcome is subject to missingness, yet some surrogate is available. Missing at random mechanism is assumed. Under conditional mean structure model, we propose a conditional empirical likelihood (CEL) method for estimation and inference. The proposed method requires no construction of estimating equations. We study CEL-based inverse probability weighted (CEL-IPW) and augmented inverse probability weighted (CEL-AIPW) estimators in details. CEL-AIPW estimator possesses
Jiann-Ping Hsu Pharmaceutical and Regulatory Sciences Student Paper Award recipient Yingqi Zhao with Tianxi Cai and Karl Peace (photo by Hongliang Shi).

double robustness property, and attains the semiparametric efficiency bound when missing mechanism and conditional mean of the outcome given surrogate and covariates are both correctly modeled. CEL-IPW estimator is consistent if the missing mechanism is correctly modeled. Numerical implementation is discussed, asymptotic distributions are established, and superior finite sample performance compared to some widely used estimators is demonstrated through simulation experiments. Data collected from an intervention study of adolescents of parents with HIV are analyzed as application.

Authors: Olivia Yueh-Wen Liao
Title: Biomarker-Based Adaptive Accrual Designs for Confirmatory Oncology Trials
Abstract: Recent scientific advances in disease biology have brought us into a new era in drug development. The newfound heterogeneity of diseases has driven the pharmaceutical industry toward the development of personalized therapy. However, with these new advances come new challenges. Using conventional clinical trial designs for targeted therapies exposes some patients who do not benefit from the treatment to unnecessary side effects. The use of conventional designs often also leads to a failure to identify existing treatment effects due to dilution in the overall population. It is therefore crucial to devise appropriate patient accrual criteria when designing confirmatory clinical trials of targeted therapies. However, typical phase II studies usually do not have enough data to support the determination of proper patient accrual criteria, especially when the treatment effect in the resistant patients is highly uncertain. In this paper, we propose an adaptive accrual design that can effectively select the population that benefits from the treatment and efficiently implements early stopping criteria (for futility and efficacy). The operating characteristics of the proposed design are demonstrated by simulation studies. Some potential issues with these kinds of trials and the proposed methodology are also discussed.

Authors: Sy Han Chiou, Junghi Kim, and Jun Yan
Title: Semiparametric Multivariate Accelerated Failure Time Model with Generalized Estimating
Equations

Abstract: The semiparametric accelerated failure time model is not as widely used as the Cox relative risk model mainly due to computational difficulties. Recent developments in least squares estimation and induced smoothing estimating equations provide promising tools to make the accelerate failure time models more attractive in practice. For semiparametric multivariate accelerated failure time models, we propose a generalized estimating equation approach to account for the multivariate dependence through working correlation structures. The marginal error distributions can be either identical as in sequential event settings or different as in parallel event settings. Some regression coefficients can be shared across margins as needed. The initial estimator is a rank-based estimator with Gehan’s weight, but obtained from an induced smoothing approach with computation ease. The resulting estimator is consistent and asymptotically normal, with a variance estimated through a multiplier resampling method. In a simulation study, our estimator is up to three times as efficient as the initial estimator, especially with stronger multivariate dependence and heavier censoring percentage. Two real examples demonstrate the utility of the proposed method.

Authors: Xueying Chen, Minge Xie

Title: A Split-and-Conquer Approach for Analysis of Extraordinarily Large Data

Abstract: If there are extraordinarily large data, too large to fit into a single computer or too expensive to perform a computationally intensive data analysis, what should we do? To deal with this problem, we propose in this paper a split-and-conquer approach and illustrate it using a computationally intensive penalized regression method, along with a theoretical support. Consider a regression setting of generalized linear models with n observations and p covariates, in which n is extraordinarily large and p is either bounded or goes to \( \infty \) at a certain rate of n. We propose to randomly split the data of size n into K subsets of size \( O(n/K) \). For each subset of data, we perform a penalized regression analysis and the results from each of the K subsets are then combined to obtain an overall result. We show that the combined overall result still retains all the desired properties of penalized estimators such as the model selection consistency and asymptotic normality under mild conditions. When K is less than \( O(n^{1/3}) \), we also show that the combined result is asymptotically equivalent to the corresponding analysis result of using the entire data all together, assuming that there were a super computer that could carry out such an analysis. In addition, the split-and-conquer approach involves a random splitting and a systemic combining. We demonstrate that the approach has an inherent advantage of being more resistant to false model selections caused by spurious correlations, and we further establish an upper bound for the expected number of falsely selected variables and a lower bound for the expected number for truly selected variables. Furthermore, when a computational intensive algorithm is used in the sense that its computing expense is at the order of \( O(n^a) \), \( a > 1 \), we show that the split-and-conquer approach can substantially reduce computing time and computer memory requirement. The proposed methodology is demonstrated numerically using both simulation and real data examples.
Dear ICSA members,

It has been almost six years since the central office of ICSA (OICSA) was established. The central office has taken on more and more tasks over these years. I would like to take this opportunity to introduce the OICSA and thank all parties for their support and help.

OICSA was established in 2006 by the ICSA Executive Committee at the request of Dr. Karl Peace to memorialize the importance of ICSA to his late wife, Dr. Jiann-Ping Hsu (http://jphcoph.georgiasouthern.edu/about/hsu), who was active in and provided great contribution to the ICSA, particularly in the early years of its growth. The purpose of the OICSA is to assist the ICSA to function more efficiently, appropriately and professionally, so that ICSA members are better served. Currently, OICSA provides the following services: (1) membership enrollment, renewal and update, (2) necessary assistance to the Executive Director, (3) ICSA Bulletin distribution, (4) communication and assistance to different parties within ICSA, such as committees and members, for various of tasks, (5) webmaster services, including but not limited to posting documents on web and maintenance of the www.icsa.org and ICSA server, (6) emailing of the ICSA e-newsletter, (7) helping ICSA members access on-line issues of Statistica Sinica and Statistics in Biosciences as needed, (8) hosting office hours, (9) processing and posting job lists on ICSA website, (10) helping the local committee for ICSA symposium, and (11) hosting the ICSA informational desk at Joint Statistical Meetings. The office will continue enriching services as needed to better serve the entire ICSA.

OICSA is incubated in the Jiann-Ping Hsu College of Public Health (JPHCOPH) at Georgia Southern University. Currently, ICSA supports a Biostatistics graduate student at OICSA. Three graduate students have worked at this position so far: Chunfeng Ren, Adam Chen, and Jingxian Cai. Their hard work on a daily basis makes great contributions to OICSA and ICSA. To ensure smooth operation at OICSA, some professors and staff provide unremunerated help. Lili Yu (Assistant Professor), Karl Peace (Professor) and Charles Hardy (Professor and former Dean of JPHCOPH) supervise OICSA. Ruth Whitworth, the IT support in JPHCOPH, provides great help on webmastering for the ICSA website. The office team members enjoy serving the ICSA and try hard to provide better and better service to this association.

Office of ICSA at Jiann-Ping Hsu College of Public Health, Georgia Southern University.

The office’s growth and continued success depends on help from all parties. Here, we would like to thank the presidents for their support. Special thanks go to the Executive Directors, Ming-Hui Chen and Shu-yen Ho, for their advice, help and understanding. Thank Simon Gao for his prompt help on IT-related issues. In addition, thanks go to the Editors of the ICSA Bulletin, Fang Yu and Jun Yan; the ICSA treasurer, Lynn Kuo; the committee chairs; and all members for their kindness, cooperation, and input.

To provide excellent service to all members, OICSA would like to hear from our members about suggestions or ideas on improving the work and functionality of the office. Please feel free to contact and discuss with us any issues you may have related to OICSA.

Best regards,

Lili Yu
OICSA
Assistant Professor
Department of Biostatistics
Jiann-Ping Hsu College of Public Health
Georgia Southern University
2012 Report on the ICSA Journal Statistics in Biosciences

Xihong Lin, José Pinheiro and Hongyu Zhao

Statistics in Biosciences (SIBS), the ICSA applied statistical journal, was launched in 2009, in partnership with Springer. It aims at development and application of statistical methods and their interface with other quantitative methods, such as computational and mathematical methods, in biological and life science, health science, and biopharmaceutical and biotechnological science. SIBS has published 7 issues, with two issues a year. The editorial board consists of 20+ associate editors.

In the last three years, with the support of the SIBS editorial board, the ICSA leadership and its members, the journal has flourished. By the end of 2011, the number of submissions has steadily increased. The number of downloads of the published papers from the Springer SIBS sites has doubled. SIBS has online subscriptions by 154 institutions/libraries worldwide. A total of 4,794 institutions worldwide have online exposure to the journal as part of an online deal with Springer (consortia, multi-site licenses, and site licenses). The ICSA members can have online access to SIBS free of charge through the ICSA website.

In addition to journal subscriptions, Springer also sends out Table of Contents (ToC) alerting. In 2011 Springer sent out a total of 9.3 million ToC alerts to over 682,000 subscribers. Researchers can easily register for this free service on the journal’s homepage. The ToC Alerts inform readers when a new issue is available online.

With the strong support of the editorial board, SIBS offers fast and high quality reviews. The average review time from submission to final acceptance of a new paper was about 5 months in 2011. The average time from acceptance of a paper to its appearance online first at the Springer SIBS website is about 1 month.

An application of SIBS into the SCI index database is currently under review, and an application of SIBS into PubMed is underway.

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New Fellows of ASA and IMS

2012 ASA Fellows

Mousumi Banerjee, University of Michigan, Ann Arbor, Michigan  For outstanding and sustained research, collaboration and mentoring involving statistical methods, theory and design for clinical trials, and for service to the profession.

Sudipto Banerjee, University of Minnesota, Minneapolis, Minnesota  For theoretical, methodological and applied research in spatiotemporal statistical modeling, especially as applied to problems in environmetrics, ecology, occupational health, agriculture and economics, for professional work at the local and national levels and for editorial service to the profession.

Dongseok Choi, Division of Biostatistics, Oregon Health & Science University, Portland, Oregon  For contributions to statistical methods in bioinformatics and spatial modeling, service to the statistical profession and to biostatistics education.

Scott R. Evans, Harvard School of Public Health, Wrentham, Massachusetts  For excellence in the design and analysis of clinical trials, consulting and education in clinical research, methodological development, and for outstanding leadership and service to the ASA and the statistics profession.

Gareth James, University of Southern California, Los Angeles, California  For outstanding, impactful research contributions on contemporary statistical theory, methods and applications in the areas of functional data analysis and high-dimensional variable selection, for excellence in teaching, and for conscientious service to the profession.

A. James O’Malley, Harvard Medical School, Boston, Massachusetts  For novel use of Bayesian statistics, multivariate-hierarchical modeling, causal inference and social network analysis to solve problems in health policy and health services research, for improving evaluation of treatments and quality of health care, and for leadership in health policy statistics.

Liang Peng, Georgia Institute of Technology, Atlanta, Georgia  For significant research in extreme value theory, nonlinear time series and nonparametric statistics, with an emphasis on applications to actuarial science and risk management.

José C. Pinheiro, Janssen R&D, Raritan, New Jersey  For the development of novel methods and software in mixed-effect models and dose finding; for influential efforts in statistical consulting; for important contributions to statistical education through book authorship and training; and for outstanding leadership in service to the profession and the ASA.

Abdul J. Sankoh, Vertex Pharmaceuticals, Department of Biometrics, Cambridge, Massachusetts  For fine research contributions to the field of biostatistics, and the enhancement of clinical trial design and data analysis.

Thaddeus Tarpey, Wright State University, Dayton, Ohio  For influential contributions to statistical research and applications, particularly in the areas of multivariate analysis and for excellence in teaching and dissemination of statistical knowledge.

Colin O. Wu, Office of Biostatistics Research, Division of Cardiovascular Sciences, National Heart, Lung & Blood Institute, Bethesda, Maryland  For innovative and fundamental research in mathematical statistics, especially in methods for longitudinal data analysis; for extensive contributions to innovative design and analysis of clinical studies in cardiovascular disease and hematological disorders and broad impact on aplastic anemia patient care and ethics of clinical trial execution.

Kelly Hong Zou, Pfizer Inc., New York, New York  For outstanding contributions to receiver-operating characteristic methodology, particularly in the areas of nonparametric and parametric transformation classification methods; for key contributions to diagnostic medicine and medical imaging research; and for innovative designs.
2012 IMS Fellows

David Banks, Duke University  For contributions to bootstrap analysis, network analysis and adversarial risk analysis, as well as important contributions to applications. For extraordinary service to the profession including a term as editor of JASA.

Daniel Francis Heitjan, the University of Pennsylvania  For significant contributions to the theory and methodology of inference from incomplete data; for outstanding applications in cancer, cardiovascular medicine, health economics, and smoking cessation research; for distinguished editorial service.

Samuel Kou, Harvard University  For influential and pioneering contributions to stochastic modeling and statistical inference in biophysics, and to Monte Carlo, Bayesian and nonparametric methods.

Tapabrata Maiti, Michigan State University  For significant research contributions in small area inference, inference for mixed models, and Bayesian methodology for panel-count data.

People News

Board of Regents Announces Karl E. Peace Recipient of Hall of Fame Alumni Award

The Jiann-Ping Hsu College of Public Health of Georgia Southern University (GSU) biostatistics professor and Georgia Cancer Coalition Distinguished Cancer Scholar, Karl Peace, Ph.D., was presented with the 2012 University System Board of Regents’ Hall of Fame Award on March 31, 2012 in Atlanta. Peace was one of only three recipients to receive the honor.

The award was established by the Board of Regents to honor those who exemplify superb leadership and support of higher education in the state of Georgia. Recipients are nominated by their alma mater and are selected by an external panel based on their outstanding accomplishments and contributions to their institution.

ASA Announces the Karl E. Peace Award

The Karl E. Peace Award for Outstanding Statistical Contributions for the Betterment of Society, established in 2012, recognizes statisticians who have made substantial contributions to the statistical profession and to society in general. The award was established by Christopher K. Peace, son of Karl E. Peace, on behalf of the Peace family to honor the life work of his father.

Jeff Wu to Deliver the Deming Lecture at JSM 2012

Professor Jeff Wu from Georgia Tech has been selected to deliver the Deming Lecture at the JSM on Tuesday, Jul 31, 4:00 p.m. on “Quality Evolution and Revolution: From Autos and Chips to Nano and Bio”.

Bin Yu Elected IMS President-Elect

Bin Yu, Chancellor’s Professor at the Department of Statistics and the Department of Electrical Engineering & Computer Science, University of California, Berkeley, has been elected President-Elect of IMS (Inst of Mathematical Statistics). The IMS is a leading international professional and scholarly society devoted to the development, dissemination, and application of statistics and probability. The Institute currently has about 4,500 members in all parts of the world.
Editorial: The first ICSA Pao-Lu Hsu Award will be announced in August, 2012. We have organized two articles in memory of Prof. Hsu: one from a personal perspective by Prof. Dihe Hu, a former student and colleague of Prof. Hsu, now Professor Emeritus of Mathematics, Wuhan University; the other from an academic perspective by Jiading Chen and Zhongguo Zheng, Professors Emeritus of Statistics from Prof. Hsu’s home department at Peking University. The first article was based on a Chinese version written in 2010 at the occasion of the 100th birthday of Prof. Pao-Lu Hsu. Knowing that the ICSA Bulletin is interested in an memorial article on Prof. Hsu in coordination with the ICSA Pao-Lu Hsu Award, Prof. Hu happily agreed to rewrite a shorter version in English. The full Chinese version is available at the webpage of the Department of Probability and Statistics, School of Mathematical Sciences, Peking University, [http://www.math.pku.edu.cn/teachers/Hsu/Hudihe-Hsu-100.pdf](http://www.math.pku.edu.cn/teachers/Hsu/Hudihe-Hsu-100.pdf). More memorial articles on Prof. Hsu can be found at [http://www.math.pku.edu.cn/teachers/Hsu/articles.htm](http://www.math.pku.edu.cn/teachers/Hsu/articles.htm). We are very gratefully to Prof. Dayue Chen, Chairman of the home department of Prof. Hsu at Peking University, for his tremendous help in soliciting the two articles and proofreading them.

In Memory of My Mentor Pao-Lu Hsu

Dihe Hu

In this article I intend to introduce some life stories and academic contributions of Professor Pao-Lu Hsu who was worldwide famous as one of the founders of mathematical statistics and the father of probability theory and statistics in China, to show my deep respect to him.

Apt. #8 of Courtyard #3 in Tong House

If you enter Peking University from the west entrance and go straight to pass a stone arch bridge, you can see a square lawn with an ornamental column on each side. Just opposite to the lawn is the Administration Building of Peking University, which is a traditional Chinese building from the early 20th century with beautiful craft works and Chinese style paintings. Going southeast from the Administration Building for about 500 meters, you would see a group of one story houses, collectively known as the Tong House, with big willow trees, bamboos and lilac trees scattered around. Some of these houses were courtyards, consisting of a central court and rooms around, which were quite typical in old Beijing. During 1950–1970s, most of the distinguished professors in Peking University lived in Yunnan Garden (燕南园), Yandong Garden (燕东园), Jingchun Garden (镜春园), and so on. Compared to these residential areas, the Tong House was much less known. In fact Apt. #8 of Courtyard #3 in Tong House (佟府丙八号) was simple and humble. Prof. Hsu lived here from the early 1950s to 1970 until he passed away. This apartment had four rooms in two columns. On the right hand of the entrance there was a four-square-meter-kitchen and at the end of the lobby there was a small storage room. Ms. Zhang Jing-Zhao (张景昭) and her family lived in the two rooms on the right of the lobby. Prof. Hsu lived in the other two relatively smaller rooms on the left. The one closer to the entrance served as his living room, which was 14 square meters large, and the other one was his bedroom. Fortunately this bedroom had its own bathroom.

His living room was arranged in this way: on the east wall hung a blackboard, along the north wall were two ceiling-high bookshelves, along each of the west and the south walls laid an armchair, in the middle of the living room was a square coffee table, and the rest furniture were several wooden stools and two thermos bottle with bamboo shells. This living room was actually multi-purposed: when Prof. Hsu held seminars, it was used as a classroom; when the faculty of probability and statistics gathered, it served as a meeting room; when Prof. Hsu looked for math literatures, it was a library; when Prof. Hsu dined, it was a dining room; only when he had visitors or companies, it was used as what it was designed to be, living room.

Prof. Hsu had very simple meals each day: three bottles of milk, two or three dishes of meat or vegetable for lunch and supper. His meals were always quite light, since he used to have pulmonary and stomach trouble.

Ms. Zhang Jing-Zhao was in the Math Department in the National Southwestern Associated University for her college education when Prof. Hsu was a professor there. She was asked to take care of...
the daily life of Prof. Hsu when they shared the apartment. She hired a housekeeper for the two families and she sometimes came to dine with Prof. Hsu. Since there was no extra room, the housekeeper had to come every morning and leave every evening.

Prof. Hsu seldom worked in his living room, he spent most of his working time in his bedroom. Leaning on his bed, he held a square board with scratch paper on it to write papers or lecture notes. Like many mathematicians, he often worked at night. Every time he felt hungry in the middle of his work, he had a piece of chocolate. During the period of 1960–1962, even a piece of chocolate was not available.

Prof. Hsu had little leisure time. When he felt tired, he took a short nap or listened to the radio. I even remember the brand of his radio, Panda, which was popular in 1950s. Listening to the radio was almost the only way for him to know what was going on in the world. And he also relied on the radio to enjoy Peking Opera or Kunqu Opera, one of the oldest extant forms of Chinese opera. I heard that Prof. Hsu was very knowledgeable on Chinese traditional literature and arts. He could even perform Kunqu Opera as good as a professional actor when he was young.

In the 1950s, Prof. Hsu usually took a break in summer and winter vacations for one week or two. Considering his health condition, the university sometimes suggested that he should have his vacation abroad, but he always insisted that one week in a hotel in the downtown Beijing would be a wonderful treat for him. In his vacations, he normally went to listen to Peking Opera, Kunqu Opera, concerts or visit some of his relatives in downtown. But after middle of 1960s, Prof. Hsu did not have any vacations at all, he stayed home almost all the time.

It would be a surprise for many people that such a prestigious scholar, who had made great contributions to Chinese academic society, lived such a humble life. Now the Tong House does not exist anymore. If it had still been there, we would have had opportunities to recall his life stories there. The old time has gone with the wind, the only thing we could do is to keep all our respect and memories in our mind.

Noble and Grace

Prof. Hsu was born into a scholarly family in the city of Hangzhou. There were seven famous scholars among his ancestors back in Qing Dynasty and the family was once bestowed an inscribed board with “seven sons acknowledged in the royal court” (七子登科), by one of the emperors. Prof. Hsu of course received authentic education in Chinese literature and history when he was young. Later he moved to Beijing to study in Huiwen High School (which used to be one of the most famous missionary schools in Beijing) and then had his college education in Tsinghua University. At the age of 26 he went to England to study at University College London under the supervision of Prof. Neyman. The training and education he received during this period had not only set a solid academic foundation for him but also remolded his mind with the thoughts of democracy and science.

It has always been well acknowledged in Chinese academic society that Prof. Hsu had made significant contribution to mathematics and statistics. In 1948, Prof. Hsu was among the first academicians of the Academia Sinica for his outstanding and pioneering work. Actually he was a scientist with remarkable background and accomplishment in other fields too, such as history, literature and so on. He always insisted that a scientist should talk and write not only with accuracy but also with impeccable grammar and beautiful rhetoric. I learned a lot about how to write a mathematical paper with beautiful Chinese when he helped me go through my manuscripts. He applied this principle as well when he translated some math terminologies from English to Chinese. In 1963, he taught us general topology in the seminar. His lecture note was just an excellent example for us. In fact he only used about 30 thousands Chinese characters to present the main content of his course. Even in daily language he insisted accuracy. Once a relative of his said that he studied “arithmetic” in Tsinghua University, he immediately pointed out that it should be “mathematics”. Of course he was not so serious all the time, he had a good sense of humor as well.

In the 1950s we had to follow the Soviet Union in every aspect. And in each working unit there were some Soviet experts to instruct the Chinese to do things in the right way according to what they did at home. At that time there was a woman professor in Mechanics from Leningrad University (now St. Petersburg) working in the Department of Mathematics and Mechanics at Peking University. Following their rules each year we had to make teaching and research plans for the probability and statistics group. Prof. Hsu was the director of the group and I was his secretary. When I did not know how to write the research plan, he told me how to
Looking Back

get around this kind of nonsense: “The papers I just finished will go for the plan for next year and we will certainly finish our plan successfully.” Like other professors he did not always agree with those Soviet professors, but he never said anything mean or sharp against them.

From 1950s to 1960s Peking University was the leading research institute of probability and statistics in China. In the seminars held by Prof. Hsu, young people were encouraged to ask any questions and even to challenge professors, which was unusual for Chinese at that time. His personality and the atmosphere in the seminar attracted many young people from other institutes and universities, which nurtured and promoted the community of probability and statistics in China a lot. We were really impressed by his broad knowledge. He was not only remembered for his academic accomplishments, but also for his character and his integrity.

Foresight and Sagacity

In 1930s Kolmogorov set the mathematical foundation for probability, so that it became a branch of mathematics and developed quickly. Almost at the same time in England, statistics, especially biometrics, medical statistics, agriculture statistics and industrial statistics, made rapid progress and were widely applied in practice. We all know it is very important in inferences to choose statistics and their distributions and analyze the errors in statistics. During the first few years after he received his PhD, Prof. Hsu did a series of pioneering work on statistical inferences and multivariate analysis. He introduced the theory on matrix, the theory on functions and the measure theory to statistics, which enhanced the mathematical foundation for statistics and gradually led to the formation of mainstream mathematical statistics. It can be seen that Prof. Hsu was one of the founders of mathematical statistics.

When he came back to Peking University in 1947 from the United States, although the academic society in China was not so active and international exchanges were not so convenient either, Prof. Hsu tried very hard to lead a group to the frontiers of probability and statistics and catch up with the mainstreams. He realized that the classical limit theory in probability and the theory on stochastic processes were two active branches, therefore apart from the effort on statistics, he led two groups of young faculty members to study the limit theory of independent random variables and Markov processes respectively. Prof. Hsu himself had also done important work on the limit theory. Unfortunately, some of the work remained unpublished because of poor communications with the latest progress, and mathematicians in other countries published similar works first.

In 1956 we read and discussed “Limit distribution of the sum of independent random variables” by Gnedenko and Kolmogorov under the supervision of Prof. Hsu. He thought that we should pay attention to Donsker’s work on invariance principles and Prokhorov’s work on advanced limit theory, and that there had to be interesting problems on those topics. At the same time, he tried to arrange Prokhorov to visit Peking University to introduce his recent work.

In order to promote research on stationary processes, Prof. Hsu first asked the department to send Jiang Ze-Pei (江泽培) to visit Moscow State University for three years. Having done beautiful works on stationary processes during his visit to the Soviet Union, Prof. Jiang came back to led a seminar on stationary processes, and then supervised students to work on time series, just as Prof. Hsu planned long time before.

Prof. Hsu came to realize very early that theories on Markov processes would be one of the most active topics in probability. At that time, potential theory in probability and semigroup theory of the operators for Markov processes were at the frontier of probability theory. He gave sequential lectures on those topics and chose related papers for us to read. He brought us to the frontiers of these areas in one or two years. Apart from sending young faculty members abroad, he also invited Prof. Dynkin to Peking University to give lectures. Unfortunately when Dynkin visited us in 1958, China was in the “Great Leap Forward”, and we hardly had enough time to make benefit from his lectures because of those endless political meetings. Although not every one of his plans was carried out smoothly, the development of probability and statistics in China had made great progress because of Prof. Hsu’s effort and foresight.

In 1956 a 12-year master plan for the development of sciences was worked out and probability and statistics was one of the three branches in mathematics which were given priority to support and develop. Of course Prof. Hsu was in the leading position to promote the research and the education of probability and statistics in China. He took the following five actions:

1. Training qualified teachers for universities. He first chose 54 senior students from
Peking University, Sun Yat-sen University and Nankai University to form a special class, joined by some instructors from universities which were in need of faculty in probability and statistics. In the mean time, he invited Profs. Wang Shou-Ren (王寿仁) and Zhang Li-Qian (张里千) from the Institute of Mathematics of the Chinese Academy of Sciences, Profs. Zheng Zeng-Tong (郑曾同) and Liang Zhi-Shun (梁之舜) from Sun Yat-sen University to give lectures systematically on Measure Theory, Limit Theory in Probability, Markov Chains, Mathematical Statistics for that special class. I was a member of that class.

2. Making outlines for curriculums and writing textbooks. Prof. Hsu set the core courses for students majored in probability and statistics: Measure Theory, Limit Theory in Probability, Stochastic Processes, and Mathematical Statistics. In addition, students could choose one or two courses according to their research interests from the followings: Markov Processes, Stationary Processes, Game Theory, Queuing Theory, Sampling Theory, Statistical Experimental Design and so on. Before 1956 the Department of Mathematics and Mechanics at Peking University only offered a basic course in probability theory, and the textbook was “Probability” by the Soviet mathematician Gnedenko. Prof. Hsu thought that we should write some textbooks based on the materials used in the seminar, and that some classical textbooks in the west should be translated into Chinese. Under his supervision “An Introduction to Probability Theory and Its Applications” by Feller was first translated. Unfortunately, before his plan had been fully carried out, the Great Cultural Revolution began and some of the textbooks in the plan never appeared.

3. Inviting foreign scholars to give lectures. Since at that time we could not communicate with mathematicians in the West, Prof. Hsu made a list of probabilists and statisticians in the East Europe, including Eugene Dynkin and Yuri Vasilevich Prokhorov from the Soviet Union, and Marek Fisz and Kazimierz Urbanik from Poland. In 1957 Prof. Fisz visited us and gave lectures on multivariate analysis and sampling theory, and Prof. Urbanik introduced generalized stochastic processes to us. As mentioned before, Prof. Dynkin visited Peking University in 1958 and talked on several active topics on stochastic processes.

4. Organizing seminars. The faculty of Probability and Statistics at Peking University were divided into three groups: mathematical statistics, Markov processes, and stationary processes. The first two groups were under the supervision of Prof. Hsu himself, and the last one was mainly led by Prof. Jiang Ze-Pei. Prof. Hsu also held a seminar on Wald decomposition and sequential analysis which were related to stationary processes.

5. Promoting setting up a journal in probability and statistics. In 1950s, there were only a few mathematical journals in China. So it was quite difficult for young researchers to publish their papers. Prof. Hsu strongly insisted that we should have a journal in probability and statistics and he even planed to fund the journal with his own deposit. But the control for publication was very strict at that time. One could hardly have the approval even for an academic journal. By the time we finally started the Journal of Applied Probability and Statistics (http://aps.ecnu.edu.cn/EN/volumn/current.shtml), Prof. Hsu had left us for more than ten years.

Everlasting Memory

Prof. Hsu’s charisma and integrity deeply affected me throughout my life and his mentoring on mathematics was greatly beneficial to me.

One day in 1958 Prof. Hsu suggested to me that I should translate “An Introduction to Probability Theory and Its Applications” by Feller. I was not quite sure whether I could handle the task, for I myself at that time had not finished reading the book and I only learned English for three years in high school (Russian was the only foreign language we could learn in college). Nevertheless, Prof. Hsu promised me that he would always be there if I needed any help in my translation. Finally, I signed a contract with the Academic Press of China. After I finished the translation, he checked my draft from the beginning to the end and wrote comments while he read it. When he noticed that I always translated “now” into Chinese as in “nowadays” or “right now”, he told me that “now” in English had other meanings and I should decide which one was the most suitable by checking the context carefully. Another detailed comment was that I sometimes used a full stop when I should use a comma.
Of course encouragement was the main tone. One comment in Chapter Nine of the book said that my translation for “a random variable” was very good: “accurate in mathematics and elegant in Chinese”.

In 1959 the Division of Probability and Statistics planned to offer a course on the limit theory of probability to students majored in probability. Prof. Hsu wanted me to teach the course. He suggested that I should first write the outline of the course based on the notes of our seminar on limit theory of independent random variables and “Probability Theory” by Loève. So I did, and he discussed the outline with me. Every young faculty member in the division found him always fully supportive.

In summer 1960, the Ministry of Higher Education organized a group of specialists in various fields to promote the progress of these fields in universities nationwide. Probability and statistics was among those with high priority, so our division was required to send two instructors to that group. Prof. Jiang Ze-Pei was sent to Zhengzhou to lecture on stationary processes and I to Guiyang to teach probability theory to college teachers. By 1960 I had only three years teaching experience and had never faced students with different backgrounds and interests before. Again Prof. Hsu told me how to handle the level of the course and how to explain concepts and results clearly and straightly to those who were not specialists in this field.

Above all the help from Prof. Hsu, his mentorship on research benefited me most. He himself taught Markov chains with countable state spaces in the seminar and directed me to read “Markov Chains with stationary transition probabilities” by K-L Chung. He brought my attention to the paper “An invariance principle for certain probability limit theorems” by Donsker which got me interested in the limit theory of stochastic processes and a few of my early papers were on this topic.

Since he left London for China, Prof. Hsu had worked for several decades at Peking University and devoted himself to the development of probability and statistics in China. So many young researchers and students benefited from his help and mentoring. It was in one afternoon in the late autumn of 1969 that I met Prof. Hsu for the last time. It was just in the middle of that Great Cultural Revolution. I saw him sitting on the ground in the campus. When I went up to say hello, I came to know that there was a public political meeting to be held in Building 18 to criticize and denounced some well established professors and he was ordered to receive “re-education” there. Since he was too weak, he had to take a break on the way to that meeting. I left him speechless. A few days later I went to a labor camp in south China, along with most members of the faculty in Peking University, to receive my “re-education”. I stayed in that labor camp in Jiangxi Province without knowing anything happening in the university until one day some new comers told me that Prof. Hsu had passed away on Dec. 18th, 1970. Near his death bed was a Parker pen he had used for decades, and piles of some unfinished drafts. He worked till his last breath and nobody ever knew how much he suffered.

My memory of Prof. Hsu will be with me forever.

Acknowledgements

My daughter, Hu Xiao-Yu, who is also a probabilist, has made contributions to prepare the English version of this article. I am also grateful to the careful typing of this work by Mr. Zhang Zhi-Yang.

Academic Achievements of Professor Pao-Lu Hsu

Jiading Chen and Zhongguo Zheng

In 2010, we celebrated the 100th birthday of Professor Pao-Lu Hsu, a world-class statistician and the founder of probability and statistics in China. He was a member of the Chinese Academy of Sciences, and a Professor of Rank One at Peking University. With reverence we recall his contributions to prob-
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ability and statistics in China.

Professor Hsu was born on September 1, 1910, in Beijing, though his forefathers were natives of Hangzhou, Zhejiang Province. He was from a prominent intellectual family. In his childhood, he received solid training in both traditional Chinese and modern Western cultures (Editorial board for “Pao-Lu Hsu Memorial Collection” 2010). He graduated from Tsinghua University in 1933, majoring in mathematics. After his graduation, he worked at Peking University as a teacher. In the meantime, he published a joint paper with Tsai-han Kiang (Jiang Zehan) on the numbers of nondegenerate critical points, which showed his solid mathematical foundation and research capability. In 1936, he went to University College London, and spent four years studying mathematical statistics. During this period, with his strong mathematical skills combined with advanced statistical ideas, he wrote a series of remarkable papers. He earned his Ph.D. in 1938 and Sc.D. in 1940. From London, he returned to China accepting a professorship in the Department of Mathematics, Peking University. In 1945, he went to the United States, visiting the University of California at Berkeley, Columbia University and the University of North Carolina at Chapel Hill. In 1947, he returned to Beijing and thereafter he was engaged in teaching mathematics at Peking University for more than 20 years. On December 18, 1970, he died in his home on the Peking University campus.

Professor Hsu set the highest standard for his research work. “The value of a paper is not determined by its publication. Instead, it is validated when it is cited frequently by others later on”; “I don’t like to get famous because my papers are published on the journals with good reputation, I prefer that a journal builds its reputation because of my papers” (Editorial board for “Pao-Lu Hsu Memorial Collection” 2010). Owing to his high standard, his published papers have profound impact in statistics.

Professor Hsu’s main research areas were mathematical statistics and probability theory. Besides, his works on matrix theory and integral transformation were excellent. He was the first Chinese internationally recognized in the area of probability and statistics. In 1979, in honor of Hsu’s 70th birthday, Anderson et al. (1979) wrote on his life and work in the Annals of Statistics. (They had Hsu’s birthday as 1909, which should be 1910.) Each of them reviewed Hsu’s research in detail from different aspects: E. L. Lehmann (who was a member of the National Academy of Science) reviewed on statistical inference (Lehmann 1979), T. W. Anderson in multivariate analysis (Anderson 1979), and K. L. Chung in probability (Chung 1979). In 1981, the book entitled “Hsu Pao-Lu Collected Papers” (in Chinese, Hsu 1981) was published by the Science Press of China, with a preface by Professor Tsai-han Kiang and Professor Hsio-Fu Tuan (both were members of the Chinese Academy of Science), who highly praised Professor Hsu for his contributions to the development of the field of probability and statistics in China. Chung (1983) edited the collection “Pao-Lu Hsu Collected Papers”, published by Springer-Verlag in 1983, including almost all Hsu’s papers, with those in Chinese translated into English. In Johnson and Kotz(1997), an edited volume entitled “Leading Personalities in Statistical Science from the Seventeenth Century to the Present”, Professor Hsu was the only Chinese statistician among the 114 people who had great influence in the development of statistical science since early 17th century, along with I. Newton, C. F. Gauss, P. S. Laplace, R. A. Fisher, J. Neyman, A. N. Kolmogorov, and others.

We introduce Hsu’s academic achievements from 10 aspects.

(1) The Behrens–Fisher Problem  The first paper of Hsu in statistics was on the Behrens–Fisher problem (Hsu 1938a). Let \( X_1, X_2, \ldots, X_n \) and \( Y_1, Y_2, \ldots, Y_m \) be samples from \( N(\mu_1, \sigma_1^2) \) and \( N(\mu_2, \sigma_2^2) \) respectively, where \( \sigma_1 \) and \( \sigma_2 \) are unknown. The problem is to test the null hypothesis \( H_0 : \mu_1 = \mu_2 \). (When \( \sigma_1 = \sigma_2 \), it is solved by the \( t \)-test. The challenging point here is that \( \sigma_1 \) and \( \sigma_2 \) are not necessary equal). Hsu considered the class of statistics

\[
U = (\bar{X} - \bar{Y})^2/(A_1S_1^2 + A_2S_2^2),
\]

where

\[
\bar{X} = \frac{1}{n} \sum_{i=1}^{n} X_i, \quad \bar{Y} = \frac{1}{m} \sum_{i=1}^{m} Y_i,
\]

\[
S_1^2 = \sum_{i=1}^{n} (X_i - \bar{X})^2, \quad S_2^2 = \sum_{i=1}^{m} (Y_i - \bar{Y})^2,
\]

and \( A_1 \) and \( A_2 \) are two constants. When \( A_1 = A_2 = (m + n)/[(n + m - 2)nm] \), \( U \) is just the Student’s \( t \)-statistic \( u_1 \), and when \( A_1 = 1/(n(n-1)) \) and \( A_2 = 1/(m(m-1)) \), \( U \) is the Behrens–Fisher statistic \( u_2 \). Hsu found the series expansion for the density of \( U \) and utilized it to study the power function of the rejection area of \( \{U > C\} \) for some \( C > 0 \). He showed that the power function relies only on the parameters \( \theta = \sigma_1^2/\sigma_2^2 \) and \( \lambda = \cdots \)
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My dealt with the optimal estimator of variance in the Hsu (1938c) area of Fisher problem, the method utilizing the rejection area within the class of quadratic forms. The class is said to be an optimal quadratic estimator of $\tau_i^2$ for all $i = 1, \ldots, p$, if the variance of $Q = \sum_{i=1}^{n} (\alpha_i - 3)m_{ii}m_{ik}$ is less sensitive to variation of $\tau_i$. Hsu considered the class of quadratic form $Q = \sum_{i=1}^{n} (\alpha_i - 3)m_{ii}m_{ik}$, where $\alpha_i$ are the nonzero roots of the associated determinantial equation. Hsu (1940) considered test statistics $W = \prod(1 - \theta_i)$ and $V = \sum \theta_i/(1 - \theta_i)$ and pointed out that their asymptotic power are the same when the sample size tends to infinity.

In small sample inference, probably the most important result of Hsu’s work is the finding and proving first optimum property for the likelihood ratio test of the linear hypothesis (Hsu 1941). Without loss of generality, we present the result in the canonical form. The quadratic form $Q = \sum_{i=1}^{n} (\alpha_i - 3)m_{ii}m_{ik}$ is independent of $\alpha_i$, and the variance of $Q$ is independent of the quadratic estimator of $\tau_i$. A quadratic form $Q$ in the class is said to be an optimal quadratic estimator of $\tau_i^2$ if the variance of $Q$ reaches the minimum within the class of quadratic forms.

Let $Q = y^T \Lambda y$, where $\Lambda$ is an $n \times n$ symmetric matrix. Hsu obtained a necessary and sufficient condition for $Q$ to be an optimal quadratic estimator of $\tau_i^2$. Let $M = I - A(\Lambda^T A)^{-1} A^T$, where $I$ is the unit matrix. Let $\tau_1, \tau_2, \ldots, \tau_n$ be the values at which the quadratic function $F = \sum_{ij} \mu_{ij} \tau_i \tau_j$ takes the minimum value under the constraint $\sum_{i=1}^{n} m_{ii} \tau_i = 1$, where

$$\mu_{ij} = \sum_{k=1}^{n} (\alpha_k - 3)m_{ki}^2 m_{kj}^2 + 2m_{ij}$$

$(i = 1, \ldots, n; j = 1, \ldots, n)$, $m_{ij}$ are elements of matrix $M = (m_{ij})_{n \times n}$, $\alpha_i = \sigma^2 E_{ij}$ for $i = 1, \ldots, n$. A necessary and sufficient condition is that the matrix $\Lambda$ has the following form

$$\Lambda = MD_\tau M,$$

where

$$D_\tau = \begin{pmatrix} \tau_1 & 0 & \cdots & 0 \\ 0 & \tau_2 & \cdots & 0 \\ \vdots & \vdots & \ddots & \vdots \\ 0 & 0 & \cdots & \tau_n \end{pmatrix}.$$
Let the joint density of \( Y_1, Y_2, \ldots, Y_m, Z_1, \ldots, Z_n \) be

\[
p(y_1, \ldots, y_m, z_1, \ldots, z_n) = (\sqrt{2\pi}^n)^{-(m+n)} \exp\left\{ -\frac{1}{2\sigma^2} \left[ \sum_{i=1}^m (y_i - \eta_i)^2 + \sum_{i=1}^n z_i^2 \right] \right\},
\]

where \( \eta_1, \ldots, \eta_m \) are \( m \) arbitrary real numbers, \( \sigma \) is an arbitrary positive number, and all numbers are unknown. The problem is to test the hypothesis

\[ H_0 : \eta_1 = \eta_2 = \ldots = \eta_m = 0, \]

where \( n_1 \) is a positive integer less or equal to \( m \). Let

\[
F = \frac{\sum_{i=1}^{n_1} y_i^2}{\sum_{i=1}^{n_1} y_i^2 + \sum_{i=1}^{n} z_i^2},
\]

\[ W_0 = \{(y_1, \ldots, y_{n_1}, z_1, \ldots, z_n) : F \geq F_\alpha \}, \]

where \( F_\alpha \) is the \( 1 - \alpha \) quantile of \( F \) under the null hypothesis, i.e. \( F_\alpha \) is determined by the equation

\[ P(F \geq F_\alpha | H_0) = \alpha, \]

\[ F = \sum_{i=1}^{n_1} Y_i^2 / (\sum_{i=1}^{n_1} Y_i^2 + \sum_{i=1}^{n} Z_i^2). \]

When \( W_0 \) is used as the rejection area in the test problem, it is shown that the power function of the test has the form of \( \beta_0(\lambda) \), where

\[
\lambda = \frac{1}{2\sigma^2} \sum_{i=1}^{n_1} \eta_i^2.
\]

Hsu obtained the following result. Suppose that the rejection area \( W \) is the set of points \((y_1, \ldots, y_{n_1}, z_1, \ldots, z_n)\) satisfying the conditions: the level of \( W \) is \( \alpha \), and the power function of \( W \) relies on the parameters only through the parameter \( \lambda \), i.e. the power function has the form of \( \beta(\lambda) \). Then, \( \beta(\lambda) \leq \beta_0(\lambda) \) for all \( \lambda > 0 \).

In other words, for the problem of testing the null hypothesis \( H_0 \), the rejection area \( W_0 \) has the maximum power function within the class of rejection areas with level \( \alpha \) whose power function relies on the parameter \( \lambda \) only. This is the first result about the optimal property of \( F \)-test, and the associated theorem was called “P. L. Hsu Theorem” (Mann, 1949). This work initiated two lines of developments. On the one hand, Hsu’s work was applied to the multivariate problem, Hotelling’s \( T^2 \) and the multiple correlation coefficient (Simaiaka, 1941). On the other hand, Hsu’s paper offered a new method for obtaining all the similar tests and was formulated by means of the concept of completeness by Lehmann and Scheffé (Lehmann, 1979).

### (4) Multivariate Analysis

From 1938 to 1945, Hsu published several papers on the forefront of the development of the theory of multivariate analysis and obtained several exact or asymptotic distributions of important statistics.

A crucial element of multivariate theory is the distribution of the sample covariance matrix \( S \). Let \( X_1, X_2, \ldots, X_N \) be a sample from \( p \) dimensional normal population \( N(0, \Sigma) \), then

\[ A \triangleq (N - 1)S = \sum_{a=1}^{N} (X_a - \bar{X})(X_a - \bar{X})^T \]

has the so-called Wishart distribution \( W(\Sigma, N - 1) \).

Hsu (1939a) derived the density function of the Wishart distribution based on algebra and analysis by mathematical induction. Anderson (1979) praised that Hsu’s proof was the most elegant among all proofs available.

Hsu (1939b) obtained the joint distribution of roots of certain determinantal equation which is a fundamental result in multivariate analysis. Let \( A = \begin{pmatrix} A_{11} & A_{12} \\ A_{21} & A_{22} \end{pmatrix} \) be independent random matrices, and \( \Sigma = \begin{pmatrix} \Sigma_{11} & \Sigma_{12} \\ \Sigma_{21} & \Sigma_{22} \end{pmatrix} \) is the size of the matrix \( \Sigma \). Let \( \theta_1 \geq \theta_2 \geq \ldots \geq \theta_p \) be the roots of the determinantal equation

\[ |A - \theta(A + B)| = 0. \]

After complicated calculations, Hsu proved that the joint density of \( \theta_1, \ldots, \theta_p \) equals to a constant times

\[
\prod_{i=1}^{p} \theta_i^{\frac{1}{2}(m-p-1)} \prod_{i=1}^{p} (1 - \theta_i)^{\frac{1}{2}(n+p-1)} \prod_{i=1}^{p} \prod_{j=i+1}^{p} (\theta_i - \theta_j).
\]

Now suppose that the matrices \( A \) and \( \Sigma \) are partitioned into

\[ A = \begin{pmatrix} A_{11} & A_{12} \\ A_{21} & A_{22} \end{pmatrix}, \quad \Sigma = \begin{pmatrix} \Sigma_{11} & \Sigma_{12} \\ \Sigma_{21} & \Sigma_{22} \end{pmatrix}, \]

where \( A_{11} \) and \( \Sigma_{11} \) are matrices with size \( p_1 \times p_1 \), and \( A_{22} \) and \( \Sigma_{22} \) with size \( p_2 \times p_2 \). Sample and population canonical correlation are defined as the roots of the following equations respectively,

\[ -\lambda A_{11} \quad A_{12} \quad 0 = 0, \quad -\lambda \Sigma_{11} \quad \Sigma_{12} \quad \Sigma_{21} \quad -\lambda \Sigma_{22} \quad 0 = 0. \]

Hsu obtained the asymptotic distribution for the normalized sample canonical correlation (Chung, 1983, pp. 142–149).

Let \( A = \begin{pmatrix} A_{11} & A_{12} \\ A_{21} & A_{22} \end{pmatrix} \) be independent random matrices, where \( A \) has a noncentral Wishart distribution and \( B \) has a central Wishart distribution. Hsu considered the joint distribution of the roots of the following determinantal equation \( |A - \phi B| = 0 \). Under
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Cramér showed that

\[ F_n(x) = \Phi(x) + \psi(x) + R(x), \]

where \( \psi(x) \) and \( R(x) \) rely on the distribution of \( \zeta_1 \) and \( \lim_{n \to \infty} R(x) = 0 \). Berry obtained the formula that for all \( x \),

\[ |F_n(x) - \Phi(x)| \leq A\beta_3n^{-\frac{1}{2}}, \]

where \( \beta_3 = E|\zeta_1|^3 \) and \( A \) is an absolute constant which relies neither on \( n \) nor on the distribution of \( \zeta_1 \).

Hsu [1945] extended Berry’s method to give a simpler proof of Cramér’s result on the asymptotic expansion of \( F_n(x) \). Furthermore, instead of considering the sample mean \( \bar{\zeta} = \frac{1}{n} \sum_{i=1}^{n} \zeta_i \), Hsu investigated the asymptotic property of sample variance \( \eta = \frac{1}{n} \sum_{i=1}^{n} (\zeta_i - \bar{\zeta})^2 \). Let

\[ G_n(x) = P\left( \frac{\sqrt{n}(\eta - 1)}{\sqrt{\alpha_4} - 1} \leq x \right), \]

where \( \alpha_4 = E\zeta_1^4 \). Under the condition that \( \alpha_6 = E\zeta_1^6 < \infty \) and \( \alpha_4 - 1 - \alpha_3^2 \neq 0 \) (\( \alpha_3 = E\zeta_1^3 \)), Hsu proved that for all \( x \)

\[ |G_n(x) - \Phi(x)| \leq A \frac{\alpha_6}{\sqrt{n}(\alpha_4 - 1 - \alpha_3^2)}^{\frac{3}{2}}, \]

where \( A \) is an absolute constant. Hsu also obtained the asymptotic expansion of \( G_n(x) \) under the condition \( E\zeta_1^{2k} < \infty \) for some \( k > 3 \), and that the remainder of the expansion has an upper bound.

By the way, influenced by Hsu [1945], Chen et al. [1985] extended Hsu’s result to estimate of \( \sigma^2 \) in the linear model, and obtained a series of important results.

(5) Probability Theory and Applications Hsu’s important results in the probability theory and their applications were derived by his capability of proficient manipulation of characteristic functions. He was a true virtuoso in the method of characteristic function [Chung 1979]. His result in Hsu [1945] is a crucial improvement of Berry’s result. Suppose that \( \zeta_1, \zeta_2, ..., \zeta_n \) are i.i.d. random variables with mean zero and variance one. Let

\[ \bar{\zeta} = \frac{1}{n} \sum_{i=1}^{n} \zeta_i, \quad \eta = \frac{1}{n} \sum_{i=1}^{n} (\zeta_i - \bar{\zeta})^2 \]

and denote by \( \Phi(x) \) the standard normal distribution function. An important problem in both theory and application is the convergence rate of the normalized \( \bar{\zeta} \) and \( \eta \) towards the standard normal distribution. Let

\[ F_n(x) \triangleq P(\sqrt{n}\bar{\zeta} \leq x). \]

and size tends to infinity, where \( \bar{\zeta} \) is well known today in the large sample theorem and Taylor expansion) is a general method to consider vector sample means, and \( f \) is a smooth multivariate function. By applying the central limit theorem to the means, and by the Taylor expansion of \( f(\cdot) \), Hsu obtained the result that the limit distribution is normal or the distribution of weighted sum of squares of normal random variables. We should point out that Hsu’s method (by using central limit theorem and Taylor expansion) is a general method which is well known today in the large sample research area and is called the Δ-method.

Hsu’s result about random matrix (for example, matrices \( A \) and \( B \) mentioned above) is one of the first results of random matrix in modern research history. In the preface of the book “Random Matrices”, the author Madan Lal Mehta took Hsu [1939b] as one of the two first important papers in the random matrix theory.

To test the independence of identically distributed random variables \( X_1, X_2, ..., X_N \), Hsu considered the statistic \( T = Q/S \), where

\[ Q = \sum_{i,j=1}^{N} a_{ij}(X_i - \bar{X})(X_j - \bar{X}), \quad S = \sum_{i=1}^{N} (X_i - \bar{X})^2. \]

Let \( a_{ij} \) rely on the sample size \( N \). Under certain conditions, Hsu obtained the asymptotic expansion for distribution function of \( T \) as \( N \) tends to infinity [Chung 1983, pp. 224–228].

Besides, Hsu investigated the asymptotic behavior of function \( f(\bar{u}_1, \ldots, \bar{u}_k) \) when the sample size tends to infinity, where \( \bar{u}_1, \ldots, \bar{u}_k \) are independent vector sample means, and \( f \) is a smooth multivariate function. By applying the central limit theorem to the means, and by the Taylor expansion of \( f(\cdot) \), Hsu obtained the result that the limit distribution is normal or the distribution of weighted sum of squares of normal random variables. We should point out that Hsu’s method (by using central limit theorem and Taylor expansion) is a general method which is well known today in the large sample research area and is called the Δ-method.

(6) Complete Convergence of Series of i.i.d. Random Variable Hsu and Robbins [1947] dealt with the complete convergence of series of i.i.d. random variables, another important contribution to probability theory. Let \( \{\zeta_n, n \geq 1\} \) be i.i.d. series with common mean \( \mu \) and finite variance. They proved that for arbitrary \( \varepsilon > 0 \),

\[ \sum_{n=1}^{\infty} P(\frac{1}{n} \sum_{k=1}^{n} \zeta_k - \mu | \geq \varepsilon) < \infty. \]

This result strengthens the classical Strong Law of Large Numbers. When this property holds, the random series \( \frac{1}{n} \sum_{k=1}^{n} \zeta_k \) is called complete convergence to the common mean \( \mu \) of \( \zeta_i \). Hsu and Robbins [1947] further conjectured that the condition
of finiteness of the variance of \( \xi \) is also a necessary condition for the complete convergence to hold. Two years later, the famed mathematician P. Erdös proved the conjecture.

(7) Central Limit Theorem  Around 1940, a challenging problem was to find a solution of the most general form of the Central Limit Theorem, which drew the attention of many famed mathematicians, such as Levy, Feller, Kolmogorov and Gnedenko. Hsu was a competitor and the competition showed that he was also on the peak. Hsu (1968) was Professor Hsu’s manuscript which Hsu mailed to K. L. Chung in 1947. In this paper, Hsu independently obtained the necessary and sufficient condition under which the row sums of a triangular array of infinitesimal random variables, independent in each row, converges in distribution to a given infinitely divisible distribution. Despite the fact that Gnedenko obtained the same result in 1944, Hsu’s method is direct and has its own trait. When K. L. Chung translated the book “Limit Theorems of Sums of Independent Random Variables” by B. V. Gnedenko and A. N. Kolmogorov in 1968, he decided to include Hsu’s paper in the book as Appendix III.

(8) Characteristic Functions  Hsu was an expert in manipulating characteristic functions. He used characteristic functions as a tool to obtain distribution of certain random variables, to calculate the power function in a test problem, and to determine the limit distribution of series of random variables. He also obtained some important properties of characteristic functions.

Let \( F(x) \) be the distribution function of random variable \( X \). The characteristic function of \( F(x) \) is defined as \( f(t) = \int_{-\infty}^{\infty} e^{itx} dF(x) \). Hsu (1951) obtained the necessary and sufficient condition, in terms of the property of its characteristic function on certain interval \((-\delta, +\delta)\) where \( \delta > 0 \) is a small number, for the finiteness of the \( \beta \)th absolute moment of the corresponding distribution, i.e.

\[
M_\beta(F) = \int_{-\infty}^{\infty} |x|^\beta dF(x) < \infty.
\]

Hsu (1954) dealt with the problem of identifying a characteristic function, i.e. to find a condition under which the values of a characteristic function on the interval \((-\infty, \infty)\) are determined by the values of the characteristic function on a small interval \((-\delta, \delta)\) with some \( \delta > 0 \). It is related to the moment problem, i.e., to find a condition under which the distribution function is determined by its moments. Gnedenko found a counterexample that two different characteristic functions coincide in a small interval \((-\delta, \delta)\), where \( \delta \) is a positive number. Hsu classified characteristic functions into two classes. For a characteristic function of the first class, it is fully determined by its values in the neighborhood of zero. The second class is called by \( \hat{U} \). A characteristic function belongs to the class \( \hat{U} \) if it is equal to another characteristic function in a neighborhood of zero without being equal to it identically. Hsu gave three subclasses of the class \( \hat{U} \). The first subclass is the simplest. However it includes all the known counterexamples. The second subclass consists of those characteristic functions of some stable distributions. The third subclass is composed of characteristic functions whose corresponding distribution function \( F(x) \) has density \( p(x) \) of the following form:

\[
p(x) = O[\exp(-\frac{|x|}{\psi(|x|)})], \quad |x| \to \infty;
\]

where \( \psi(x) \) has one of the following forms:

\[
(\ln x)^\lambda, \quad (\ln x)(\ln \ln x)^\lambda, \quad \ldots \quad \lambda > 1.
\]

(9) Matrix Theory  Hsu was an expert in applying matrices as a tool to solve mathematical problems. He obtained several theorems in matrix theory. Hsu (1955a) studied the transform from square matrix \( A \) to square matrix \( B \), where all the elements of the matrices are complex numbers, \( A \to B = PA\bar{P}^{-1} \), where matrix \( P \) is nonsingular square matrix, and \( \bar{P} \) is the conjugate matrix of \( P \). If \( A \) and \( B \) can be transformed to each other, then \( A \) and \( B \) are called similar. Hsu obtained the canonical form under the sort of transformations for all matrices and a necessary and sufficient condition for two matrices to be similar.

Hsu (1955b) studied a transform from a matrix pair \( (A_1, A_2) \) to another pair \( (B_1, B_2) \), where \( A_1 \) and \( B_1 \) are matrices of the same size, with complex number as their elements. If \( (A_1, A_2) \) can be transformed into \( (B_1, B_2) \) through the following equations

\[
A_1 \to B_1 = PA_1Q, \quad A_2 \to B_2 = PA_2\bar{Q},
\]

where \( P \) and \( Q \) are nonsingular square matrices, then the two pairs are called equivalent. Hsu found the canonical form for the equivalent pairs and a necessary and sufficient condition under which two pairs are equivalent.
In a long article (38 pages in the original Chinese version and 54 pages in the English version), Hsu (1957) investigated profoundly the property of joint transformation of Hermitian matrix and a symmetric (or skew symmetric) matrix. Let $A_1$ be a Hermitian matrix (i.e., $A_1^T = A_1$), and $A_2$ be a symmetric matrix (or skew symmetric). The transformation for the pair $(A_1, A_2)$ is

$$A_1 \rightarrow B_1 = PA_1(P)^T, \quad A_2 \rightarrow B_2 = PA_2P^T,$$

where $P$ is some nonsingular matrix, and the transpose of $P$ is denoted by $P^T$. If the two pairs can be transformed to each other through these transformations, then the two pairs are said to be congruent. By a careful derivation and complex calculation, Hsu obtained the following conclusions:

(i) Let $A_1$ be a Hermitian matrix, $A_2$ be a symmetric matrix. The canonical forms of the pairs were found (there exist 7 different forms totally). A necessary and sufficient condition for two pairs to be congruent was obtained.

(ii) Let $A_1$ be a Hermitian matrix, $A_2$ be a skew symmetric matrix. The canonical forms of the pairs were found (there exist 8 different forms totally). A necessary and sufficient condition for two pairs to be congruent was obtained.

These results in Hsu’s papers are important contributions to the matrix theory. The arguments in the proof exhibited Hsu’s skills at manipulating matrices and his attention to details.

(10) Markov Process [Hsu (1958)] investigated the differentiability of probability transition function of a purely discontinuous homogeneous Markov process on the Euclidian space. Let $X$ be the $n$ dimensional Euclidian space, and $F$ be the Borel $\sigma$-field in the space $X$ and $p(t, x, E)$ be the probability transition function of a purely discontinuous homogeneous Markov process on $X$, i.e., for $x \in X, t > 0$ and $E \in F, p(t, x, E)$ is the conditional probability of the event when the process is at state in the set $E$ at time $s + t$ under the condition that the process is at $x$ at time $s$. Hsu proved the differentiability of probability transition function $p(t, x, E)$ with respect to the variable $t$. Hsu also derived several integral equations for the differential of $p(t, x, E)$ which was a generalization of the results of Austin for the probability transition function on the discrete space. Hsu’s method was more elementary than Austin’s and Hsu’s results were sharper.

In addition to the 10 aspects of his results, Professor Hsu led several seminars at Peking University in 1957–1966. Under his guidance, the participants obtained valuable results especially in the area of experimental design and order statistics. Some results were published in the journals by pen name “Ban Cheng”. Ban (1964b) deals with partial balanced incomplete block design (PBIB design). For certain design parameters, Ban Cheng obtained the condition of existence for the PBIB design with $m$-associate classes and constructed the design. Ban (1964a) investigated the limit distribution of order statistics. Let $X_1, ..., X_n$ be i.i.d. random variables with common distribution function $F(x)$ and their order statistics be denoted by $\xi_1^{(n)} \leq ... \leq \xi_n^{(n)}$. Ban (1964a) proved that under certain conditions, the series of normalized statistics $\xi_{i_k}^{(n)} (k_n \rightarrow \infty, k_n/n \rightarrow \lambda \in [0, 1])$ has one of the following distributions as the limit distribution:

$$\phi_{1}(x) = \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{x} e^{-\frac{t^2}{2}} dt,$$

$$\phi_{2}(x) = \begin{cases} 0 & x \leq 0 \\ \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{x} e^{-\frac{t^2}{2}} dt & x > 0, \alpha > 0 \end{cases}$$

and

$$\phi_{3}(x) = \begin{cases} 1 & x \geq 0 \\ \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{x} e^{-\frac{t^2}{2}} dt & x < 0, \alpha > 0. \end{cases}$$

The conditions for the common distribution function $F(x)$ to be in the domain of attraction of $\phi_i(x), i = 1, 2, 3$, were also obtained respectively in Ban (1964a).

Above we summarized Prof. Hsu’s major scientific achievements. Most of his papers were collected in Chung (1983), the edited volume of “Pao-Lu Hsu Collected Papers”, which also reflected his high standard in research quality and scientific spirit. This kind of spirit is especially important for scientists today.

Bibliography


Statisticians Supporting Late-stage Clinical Development at Merck

Jerald S. Schindler and Yang Song

Overview of Late Development Statistics at Merck

At Merck, the Biostatistics and Research Decision Sciences (BARDS) organization has a proud record of providing comprehensive analytical and methodological expertise to support Merck's strategic goals. BARDS scientists are skilled in a range of technical and scientific disciplines including research design methodology, statistical theory and methods, mathematics, computer science, epidemiology, outcomes research and health economic modeling. The organization is comprised of various functional areas which collectively are organized to provide support across all divisions of Merck spanning product discovery through manufacturing and marketing.

- Late Development Statistics (LDS) provides statistical support for late-stage clinical development, generally starting from Phase II. In certain therapeutic areas such as oncology and vaccines, LDS also supports Phase I development.
- Early Development Statistics provides statistical support for early-stage clinical development, and support of data analysis and experimental design for pre-clinical and non-clinical studies.
- Epidemiology supports the scientific study of disease, endpoints and patient outcomes to evaluate the benefits and risks of Merck products.
- Health Economic Statistics supports the development and application of quantitative scientific methods to demonstrate the economic value of Merck products to customers.
- Scientific Programming provides scientific programming to biostatisticians, epidemiologists, and health economists across the BARDS organization.

The LDS department within the BARDS organization consists of over 100 statisticians globally. Administratively, LDS is organized into 7 research groups, 5 in the US, 1 in Europe and 1 in the Asia-Pacific region, which is the newly established group based in Beijing. To better support clinical development projects, LDS statisticians are also organized by therapeutic areas (or franchises), which, to some extent in the US, align with the research groups.

Statisticians in LDS provide statistical support for the full life cycle of a clinical study. It starts with study planning, a key part of which is protocol development. The statistician will collaborate very closely with the clinical team to understand the objectives of the study and provide input on the study design, including sample size. The statistician will write certain sections of the protocol, especially the section on statistical planning and analysis. Certain studies, especially those pivotal Phase III studies intended for regulatory submission, will need more activities in the planning, including discussion with regulatory agencies, scientific input from experts or key opinion leaders, and the setup of oversight committees for the study, e.g. data monitoring committee and endpoint adjudication committee. Merck LDS statisticians have a long tradition of providing very strong support and leadership in these activities. After study planning, there are a few activities that need statistical support for study initiation. The statistician will support the preparation of randomization schedules for patient enrollment and the setup of IVRS (Interactive Voice Response System) to facilitate enrollment if applicable. The statistician will also support the development of CRF (case report form) to ensure the data points that are needed for statistical analysis can be completely and accurately collected. Sometimes, statisticians also participate in investigator meetings to help orient the physicians and study coordinators who participate in the study on the study design and objectives and train them on the conduct of the study. When a study is ongoing, statisticians would support medical monitoring of the study safety and any interim analyses of the study if applicable. At the end of the study, statisticians will provide complete analysis of the study and appropriate statistical interpretation of the analysis. In collaboration of the clinical team, LDS statisticians will further compile the analysis results and write the clinical study report.

In addition to providing statistical support for clinical studies, Merck LDS statisticians take pride in providing support of clinical develop-
ment strategies. With our quantitative expertise, we work with clinical and regulatory colleagues to devise the development strategy for clinical programs. Often times, we are able to evaluate different development strategies quantitatively and recommend the optimal one. In fact, the LDS statistician in the team is a key contributor of the clinical development plan.

The statistical support LDS statisticians provide is also important to the success of a regulatory submission. Working closely with regulatory and clinical colleagues, we help develop the submission strategy, provide timely and quality response to questions from regulatory agencies, and engage in discussions with the agencies regarding the benefit and risk of the product. For some submissions to the US FDA, a public advisory committee meeting is required to get independent expert advice on the benefit risk of the product. LDS statisticians play a vital part in the preparation of such meetings. A lot of expertise, experience and efforts are needed from the statisticians to help understand and interpret the clinical data from different angles.

Within the LDS department and more generally within the BARDS organization, there are a lot of interactions and collaborations among statisticians on various statistical and scientific topics. To standardize the approach to important, commonly-encountered statistical technical issues across the late and early development statistics departments, a committee called ELSTIC (Early / Late-stage Statistics Technical Issues Committee) coordinates the development, review and approval of guidance documents. There are various working groups under the oversight of the ELSTIC on a broad range of topics, e.g. longitudinal data analysis, multiplicity, time-to-event analysis, safety analysis, and adaptive designs. There are also other working groups to work on some special topics such as decision analysis and Bayesian methods and practice. There are regular seminar series where statisticians can volunteer to present interesting topics and share their experience in projects. To promote sharing of experience on clinical development projects, LDS statisticians conduct peer review on important deliverables of the projects. For example, TDRC (Trial Design Review Committee) provides input on clinical study design when the protocol is still at concept stage.

Merck statisticians, in LDS and in the broader BARDS organization, have a reputation of being an industry leader in statistical innovation. Merck statisticians are well known for their scientific excellence in adaptive designs, Bayesian methods, and other areas, e.g. sample size estimation and vaccine clinical trial designs, with widely quoted publications. Our statisticians are encouraged to do statistical research, especially that originating from clinical development projects and that adding value to Merck’s R&D pipeline. Every year at the Joint Statistical Meetings, statisticians from Merck make a large number of presentations. In fact, Merck is one of the pharmaceutical companies, if not the pharmaceutical company, that have the largest number of presentations. Within Merck, LDS statisticians also take leadership on innovation to improve efficiency in drug development at Merck. For example, LDS statisticians take leadership in a cross-functional initiative to increase the use of adaptive design clinical trials in clinical development strategy and develop an infrastructure to support the design and conduct of adaptive designed clinical trials.

**Experience in Oncology Drug Development — Yang Song**

Jerry has provided an overview of the LDS department. As an LDS statistician that has been working on oncology projects, I would like to share my experience in supporting oncology drug development at Merck. I am currently in one of the 5 US LDS research groups and I am excited to have learned that I will soon be assigned to the LDS research group in the Asia-Pacific region for a period to support the building of the organization in the region.
I started to work as a Merck LDS statistician supporting oncology over 5 years ago. At that time, Merck had a fairly young and small oncology franchise, compared to industry leaders in oncology. There was just a very small team of LDS statisticians supporting oncology. Over the past a few years, Merck oncology has been expanding with a much stronger pipeline. It feels very fulfilling to be part of the growth.

At Merck oncology, LDS statisticians play a key role in supporting the clinical development strategies. One of Merck oncology’s focuses is targeted therapies. We are interested in identifying the patients who are most likely to respond to particular drugs based on the molecular characteristics of their tumors. To support the strategy, LDS statisticians researched into not only statistical methods but also portfolio management approaches to evaluate different ways of developing a target therapy. Another focus of Merck oncology is novel combination therapies. There are a variety of complexities for combination development in all phases of clinical trials, from dose finding to providing confirmatory data for regulatory approval. LDS statisticians collaborate closely with clinical and regulatory colleagues and engage in discussions with external experts and regulatory agencies to advance the development of combination therapies.

Cancer clinical trials have some unique characteristics. Clinical proof of concept and sometimes even regulatory approval is based on a surrogate endpoint. LDS statisticians provide pivotal support in understanding the relationship between the surrogate endpoint and the clinical endpoint. A commonly used surrogate endpoint is often a time to event endpoint, e.g. progression-free survival, assessed by regular disease assessments, e.g. CT scans every 8 weeks. Such data are interval censored in nature in that the true event time is only known to be within an interval between disease assessments. A scientific understanding of the data requires an understanding of the interval censored nature of the data and statistical analysis consistent with generation of the data. LDS statisticians advocate the use of interval censored methods. We have evaluated the statistical properties of different methods. For registration studies, we have also discussed with regulatory agencies on the use of methods that take into account the interval censored nature of the data.

To improve efficiency to support cancer clinical trials, LDS statisticians look for ways to standardize the process for certain deliverables. For example, we have partnered with statistical programmers to standardize safety and even some efficacy tables for clinical study reports. Another example is that we have been pushing to use standardized approaches for dose finding Phase I studies, based on methodology developed by researchers at MD Anderson Cancer Center and our own customization.

I have enjoyed working on oncology drug development. In working on early phase studies, it is fun to speak to clinical colleagues to understand the biology of the disease, scientific rationale for the therapy, and their clinical insight, sometimes based on experience in individual patients. It has not only enriched my knowledge about cancer but also allowed me to collaborate in a more productive and customer focused way. In later phase studies, substantial statistical input is needed and can be critical as complex issues such as subgroups defined by biomarker, surrogate endpoint, interim analysis for futility and/or efficacy arise. It is fulfilling to be able to provide statistical guidance and know that my work would make a difference in cancer patients’ lives. It is particularly fulfilling to work on regulatory submissions. I was fortunate to be the statistical lead of the worldwide regulatory submission of a cancer product. It was intensive cross-functional collaboration effort to prepare the documentation for submission. Communication is really important not only for internal coordination of submission activities but also for interaction with regulatory agencies. It was interesting to experience different levels of statistical expertise from regulatory agencies and scientific experts worldwide. I worked in the sponsor team for the advisory committee meeting, which was part of the interaction with the US FDA for their review of the submission. During the preparation, we conducted a large number of analyses in response to possible questions from the committee. It was intense and yet fulfilling to collaborate with clinical and regulatory colleagues to translate a question into statistical inquiries, perform the analysis, interpret the results, and form a response. There are many examples of challenging questions. One example is how to evaluate and present the treatment effect size for interval censored data. We had a lot of discussion on how to put appropriate clinical interpretation for the abstract concept of hazard ratio. Another example is the analysis and interpretation of patient reported outcome data. Experts have been more and more focusing on how cancer patients feel in the evaluation of cancer therapies. Yet, such data collected in clinical trials often has a design limitation which provides very little, if any, data after patients are off therapy. This limi-
Statisticians at Work

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Bringing Statistical Innovation to Oncology Drug Development

Pandurang M. Kulkarni, Nathan H. Enas, and Yanping Wang

In an earlier ICSA Bulletin article, our colleagues Ruberg and Fu (2012) from Lilly Global Statistical Sciences shared our journey on bringing statistical innovation to life in drug development. To build on that, we would like to share with you some of the statistical innovation we have brought to the Oncology drug development and how we are making what is “advanced today, routine tomorrow”. Though there are many topics we could highlight, we are focusing here on two important topics that have major impact on the development of Oncology molecules. The first one has to do with the type of designs, and the second concerns the likelihood of success of the designs. We provide an overview of these two topics and share how we have gone about advancing drug development using analytical approaches.

Reducing Single Arm Trials by Efficiently Enabling Randomized Trials

In oncology clinical drug development, clinical trials used to test for drug efficacy have often been designed without a concurrent control group. These “single arm” studies rely on historical controls in order to assess the magnitude and significance of the new drug candidate. However, single arm trials (SAT) have severe inferential limitations, owing to bias in patient selection and evaluation, making the comparison to historical controls highly unreliable. On the other hand, randomized controlled trials (RCT) are the “gold standard” for evaluating new drug candidates, but are also more costly and time-consuming than single arm studies.

From an inferential perspective, SATs rely on a “control arm” that is completely constructed from historical patient outcomes (i.e., 100% “borrowing” from historical control), whereas traditional RCTs do not rely at all on historical patient outcomes (i.e., 0% “borrowing” from historical control). One of the arguments used for not conducting randomized trials is the extra cost and time associated with RCTs compared to the SATs. However, this cost containment has the risk that we are all too familiar with the SATs, and the Oncology community has come to realize this. Therefore, to balance the two approaches, we need to offer an alternative that can be used whenever possible. For instance, Bayesian methods can help model the continuum between SATs and RCTs based on the amount of “borrowing” of historical control information utilized within a prospective clinical trial. This continuum is the domain of the so-called Bayesian Augmented Control (BAC) design. This design begins with the RCT design, but uses Bayesian modeling to enable borrowing from historical control patient outcomes collected in prior clinical trials (borrowing $x$% depending on the appropriateness of histor-
ical data to the current trial). Thus, in cases where there is very good historical information available on the control, we could design an RCT that allocates much smaller number of patients to control arm than to the treatment arm. Cost of this RCT should be much less than the standard RCT while it is somewhat greater than SAT. On the other hand, if the historical data is not robust then one should borrow less. As one borrows less the cost of this BAC design would be closer to the standard RCT and considerably more than SAT. Even in these cases, we strongly recommend using RCTs because obviously it is clear that you do not have any good historical data to compare against and hence a single arm study would provide you with no clear decision about whether to proceed to Phase 3 and what outcome to expect in Phase 3. There are special circumstances where SAT may make sense. For example, if there are no accepted treatment options and definitive efficacy is expected (e.g., complete tumor response). In such cases, it is likely that an SAT may be acceptable and act as the pivotal study for provisional regulatory approval.

The BAC methodology has now been operationalized and simulations are made possible through the use of software called FACTS (http://www.smarterclinicaltrials.com/what-we-offer/facts/) and supported by our Advanced Analytics group of the Lilly Global Statistical Sciences function. We have utilized this methodology in numerous oncology trials, the first of which is completing in the near future. Initially this was met with caution and uncertainty. However, as clinicians understood the details and became more comfortable with the approach, and we were able to quickly simulate many scenarios using the FACTS software, we have been able to apply this innovative approach on a regular basis. Thus, what was advanced a few years ago is routine now.

As with any Bayesian design, this model affords researchers greater control over important design parameters than frequentist designs, but with this increased control comes increased responsibility to choose valid historical data and model specifications. Nevertheless, when credible and relevant historical data exist for the prospective control therapy, this design has become a method of choice for Phase II cancer trials at Lilly. Therefore, a full RCT should be the first choice, and when valid historical information exists, then BAC should be given serious consideration.

Understanding and Increasing the Probability of Study Success (PrSS)

Oncology clinical trials can be very lengthy, costly, and hard to enroll due to limited patient pool. Further, most often these trials are dealing with treating patients with potentially life ending cancers. Yet, only 34% of Phase 3 oncology drug trials with results reported from 2003 through 2010 were successful (Sutter and Lamotta 2011). Therefore, a critical question that study sponsors always ask before investing in a clinical study is how likely is it that the study is going to be successful.

Traditional statistical power does not provide a reliable answer to this question — most Phase 3 studies are powered at 80% or higher, but the success rate of Phase 3 studies is much lower than 80%.
This is so because power is the probability of success (i.e., achieving statistical significance) at an assumed effect size. The assumed effect size is often based on regulatory, payer and/or marketing requirements or needs and may not be supported by available evidence or reflect the true treatment effect. Occasionally, the effect size is estimated from available evidence, but the estimate is typically treated as a fixed constant without any variability. In short, not utilizing available data or not utilizing the data appropriately is the underlying reason that power does not reliably measure the probability of study success (PrSS).

Several authors have proposed to use the so-called “assurance”, “expected power”, or “average success probability” to quantify PrSS (O’Hagan et al., 2005; Chuang-Stein, 2006). The idea is to use available data to derive the distribution of the unknown true treatment effect and then average the power function of the new study over the distribution. The resulting average is nothing but the so-called predictive power, a hybrid of frequentist and Bayesian concepts (Dmitrienko et al., 2005; Spiegelhalter et al., 2004). The PrSS is based on available data and also accounts for the uncertainty in our current knowledge on the treatment effect, thus representing an improvement over power in quantifying the likelihood of success for the new study. Often times, the distribution of treatment effect and/or the design of a new study are quite complex, but simulation studies are very helpful in estimating the PrSS. In Lilly Oncology, we started to institute this thought process to evaluate every Phase 3 study for its PrSS, once again enabled by our Advanced Analytics group. Initially, this was difficult and harder to consume by the customers, as they are accustomed to the traditional concept of “power”. However, because of its intuitive appeal, we have been able to make this idea routine through education and use in all Phase 3 trials. We have demonstrated to the teams that PrSS helps improve study designs and inform clinical planning. This approach also has been extremely helpful to evaluate the utility of interim analysis and the ultimate PrSS. Therefore, simulating the PrSS by utilizing historical data from “proof of concept” and other trials as appropriate is a routine benefit the statisticians should provide to their clinical teams to help make better decisions and to improve the success of Oncology drug development.

In summary, with the focused effort and leadership from Oncology Statisticians and the Advanced Analytics group, we have been able to turn statistical innovation into routine practice.

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Reproducible Research: Notes from the Field

Roger Peng

Editorial: "Simply Statistics" is a blog of three biostatistics professors at Johns Hopkins University (Jeff Leek, Roger Peng, and Rafa Irizarry), who are fired up about the new era where data are abundant and statisticians are scientists; see http://simplystatistics.tumblr.com/ Dr. Roger Peng wrote on reproducible research on November 6, 2011. A slightly edited version is published here with permission.

Over the past year, I’ve been doing a lot of talking about reproducible research. Talking to people, talking on panel discussions, and talking about some of my own work (a YouTube video is available at http://www.youtube.com/watch?v=aH8dpCirW1U). It seems to me that interest in the topic has exploded recently, in part due to some recent scandals, such as the Duke clinical trials fiasco (see, e.g., a very good summary in The Economist, http://www.economist.com/node/21528593).

If you are unfamiliar with the term “reproducible research”, the basic idea is that authors of published research should make available the necessary materials so that others may reproduce to a very high degree of similarity the published findings. If that definition seems imprecise, well that’s because it is.

I think reproducibility becomes easier to define in the context of a specific field or application. Reproducibility often comes up in the context of computational science. In computational science fields, often much of the work is done on the computer using often very large amounts of data. In other words, the analysis of the data is of comparable difficulty as the collection of the data (maybe even more complicated). Then the notion of reproducibility typically comes down to the idea of making the analytic data and the computer code available to others. That way, knowledgeable people can run your code on your data and presumably get your results. If others do not get your results, then that may be a sign of a problem, or perhaps a misunderstanding. In either case, a resolution needs to be found. Reproducibility is key to science much the way it is key to programming. When bugs are found in software, being able to reproduce the bug is an important step to fixing it. Anyone learning to program in C knows the pain of dealing with a memory-related bug, which will often exhibit seemingly random and non-reproducible behavior.

My discussions with others about the need for reproducibility in science often range far and wide. One reason is that many people have very different ideas about (a) what is reproducibility and (b) why we need it. Here is my take on various issues.

- Reproducibility is not replication. There’s often honest confusion between the notion of reproducibility and what I would call “full replication”. A full replication doesn’t analyze the same dataset, but rather involves an independent investigator collecting an independent dataset conducting an independent analysis. Full replication has been a fundamental component of science for a long time now and will continue to be the primary yardstick for measuring the plausibility of scientific claims. I think most would agree that full replication is preferable, but often it is simply not possible.

- Reproducibility is not needed solely to prevent fraud. I’ve heard many people emphasize reproducibility as a means to prevent fraud. Journal editors seem to think this is the main reason for demanding reproducibility. It is one reason, but to be honest, I’m not sure it’s all that useful for detecting fraud. If someone truly wants to commit fraud, then it’s possible to make the fraud reproducible. If I just generate a bunch of numbers and claim it as data that I collected, any analysis from that dataset can be reproducible. While demanding reproducibility may be useful for ferreting out certain types of fraud, it’s not a general solution and it’s not the primary reason we need it.

- Reproducibility is not as easy as it sounds. Making one’s research reproducible is hard. It’s especially hard when you try to do it after the research has been done. In that case it’s more like an audit, and I’m guessing for most people the word “audit” is NOT synonymous with “fun”. Even if you set out to make your work reproducible from the get go, it’s easy
to miss things. Code can get lost (even with a version control system) and metadata can slip through the cracks. Even when you’ve done everything right, computers and software can change. Virtual machines like Amazon EC2 and others seem to have some potential. The single most useful tool that I have found is a good version control system, like git (http://git-scm.com/).

- At this point, anything would be better than nothing. Right now, I think the bar for reproducibility is quite low in the sense that most published work is not reproducible. Even if data are available, often the code that analyzed the data is not available. So if you’re publishing research and you want to make it at least partially reproducible, just put what you can out there. On the web, on github (http://github.com/), in a data repository, wherever you can. If you can’t publish the data, make your code available. Even that is better than nothing. In fact, I find reading someone’s code to be very informative and often questions can arise without looking at the data. Until we have a better infrastructure for distributing reproducible research, we will have to make do with what we have. But if we all start putting stuff out there, the conversation will turn from “Why should I make stuff available?” to “Why wouldn’t I make stuff available?”

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Making Reproducible Research Enjoyable

Yihui Xie

It is hard to convince people to think about reproducible research (RR). There are two parts of difficulties: (1) tools used to be for experts only and (2) it is still common practice to copy and paste. For some statisticians, RR is almost equivalent to Sweave (R + \LaTeX). I love \LaTeX, but \LaTeX is still hell to many people. I had an experience of teaching Sweave in a stat-computing class at Iowa State University, and I can tell you their horrible faces after I taught them \LaTeX in the first half of the class. I will never do that again.

But RR is really important. I recommend you to watch this video if you have not heard of the Deception at Duke to see how improper data processing killed patients: http://www.cbsnews.com/video/watch/?id=7398476 then you should feel guilty when you copy and paste as a statistician. I fully respect the seminal work of Sweave, but in my eyes, it is really a half-done project which did not make much progress in the past few years. I suggested a few features to the R core team, which were often rejected. I understand that R is too big to make substantial changes. As a useR, you always have the right to vote by packages, so I wrote the knitr package to fully implement what I thought would be a good engine for RR with R.

The basic idea was the same: to mix code and text together, then compile the whole document with code being executed, and you get a report without copying/pasting anything since the code will faithfully give you results. The design was very different from Sweave, however: knitr is not restricted to a specific format like \LaTeX any output format is possible, including HTML, Markdown and reStructuredText. I will ignore \LaTeX in this article, although it took me much more time to work on than other formats.

I use Github extensively and learned markdown there. For those who are not familiar with markdown, it is an extremely simple language and you can learn it in five minutes at most: http://en.wikipedia.org/wiki/Markdown. It was almost trivial for me to add support for markdown...
in **knitr** so we can mix R code and markdown text together and compile reports quickly. That was the beginning of the story.

Later, the developers of RStudio (http://www.rstudio.org) saw the work of **knitr** and decided to add support to it. First we finished the work with Sweave documents, which was painful but rewarding (well, that is LaTeX). Before that I had finished adding the **knitr** support in LyX — an excellent front-end of LaTeX and RR became enjoyable somehow, but only enjoyable for me and perhaps also some other LyX users. We could write LaTeX easily and click the button to get a PDF report from LyX, which was quite handy (http://yihui.name/knitr/demo/lyx/).

After the Sweave work was done, I suggested markdown to RStudio developers, and fortunately they listened. The progress was fast; soon we had a format named R markdown in RStudio. That was when I believed RR became accessible to the general audience.

And suddenly a golden glow descended on me, and all my sins were washed away…

Many people seem to have been waiting for a simple format like R markdown for a long time. The only thing you need to do for a reproducible report is to write code and text. When you write in LaTeX there are tons of rules to remember like which characters need to be escaped, or how to write a back-slash or tilde, whereas in markdown, you feel like writing emails.

JJ Allaire (one of the RStudio authors) and I were invited to give a talk (http://yihui.name/slides/2012-knitr-RStudio.html) at useR! 2012 on RR a few days ago, and we successfully convinced quite a few people to RR and R markdown. One of my points was that RR should be made enjoyable. If people suffer from tools all the time, there is no hope for RR to become the common practice. To ask people to go to the right way, we just need to make the right way easier than the wrong way (one smart guy in the audience said this after we gave a talk to the Twin Cities R User Group). Chris Fonnesbeck, an instructor in Biostatistics at Vanderbilt University, decided to completely ban Word documents in his BioS301 this Fall. I admire his courage, and I am evil to be happy to see Word die, but I will be happier if the students can see why Word sucks and how **knitr**/RStudio/R markdown can make things much easier and more beautiful. As I proposed at useR! 2012, we should really start to train students to do their homework assignments in a reproducible manner before they do research in the future. This is not hard now.

Kevin Coombes and Keith Baggerly are the two heroes (and detectives) who revealed the Duke scandal, which I mentioned before. They have been trying to promote Sweave, and I was thrilled at useR! 2012 that Kevin used one slide to introduce **knitr** in his invited talk. I was also excited when Keith told me R markdown was cool and he was going to use it in his reports.

There are many other features in **knitr** which make RR enjoyable. For example, code is highlighted by default so that plain text will not become pain text; for users who do not care about coding styles, their code will be automatically reformatted with the formatR package to make ugly code more readable (Martin Maechler does not like this but he is an R expert and knows how to format R code); figures will never exceed the page margin in LaTeX output; you do not have to use dirty tricks in order to get multiple figures per chunk; … In all, we get beautiful reports by default, although the beauty here is highly opinionated.

It is always enjoyable when we can embrace the web, where we have lots of fancy technologies. Markdown can be easily translated into HTML, so we can build web applications with **knitr** as well. Two examples:

1. Rpubs.com (http://rpubs.com): you can publish your reports to this website (hosted by RStudio) freely from RStudio, and you can see there have already been a couple of nice reports (just forget about emailing ugly Word documents back and forth)

2. An OpenCPU demo: http://public.opendcu.org/apps/knitr/ (you do not need anything but a web browser, then you can compile a report in the cloud)

You can see what other people have been doing with **knitr** at http://yihui.name/knitr/demo/showcase/. Let’s stop the old habit of copy and paste. Let the code speak, and in code we trust.

Yihui Xie
PhD student
Department of Statistics
Iowa State University
xie@yihui.name
Tel: (+1) 515-203-2465
http://yihui.name
Upcoming Events

Joint Statistical Meetings 2012
July 28 — August 2, 2012
San Diego, CA, USA
http://www.amstat.org/meetings/jsm/2012/index.cfm

Computational Advertising Summer Program
August 6 — August 17, 2012
Research Triangle Park, NC, USA
http://www.samsi.info/

Data-Driven Decisions in Healthcare Program Opening Workshop
August 26 — August 29, 2012
Research Triangle Park, NC, USA
http://www.samsi.info/

Statistical and Computational Methodology for Massive Datasets Program Opening Workshop
September 9 — September 12, 2012
Research Triangle, NC, USA
http://www.samsi.info/

IAOS 2012 Official Statistics: Getting Your Messages Across
September 12 — September 14, 2012
Kiev, Ukraine
http://iaos2012.ukrstat.gov.ua/

BASS XIX 2012
November 5 — November 9, 2012
Savannah, GA, USA
http://bass.georgiasouthern.edu/

The 68th Deming Conference on Applied Statistics
December 3 — December 7, 2012
Atlantic City, NJ, USA
http://demingconference.com/

ASA Conference on Statistical Practice 2013
February 16 — February 18, 2012
New Orleans, Louisiana, USA
http://www.amstat.org/meetings/csp/2013/index.cfm

29th European Meeting of Statisticians
July 20 — July 25, 2013
Budapest, Hungary

Professional Opportunities

For details and contacts about all posts, see http://www.icsa.org/job/index.html

Head of Department of Applied Mathematics, The Hong Kong Polytechnic University
Experience in fund-raising will be an additional advantage. Terms of appointment and remuneration package are negotiable and highly competitive.

Faculty Position in Statistics or Econometrics, Central University of Finance and Economics (CUFE)
School of Statistics at CUFE invites applications for full-time tenure-track positions of all ranks (Assistant, Associate, and Full Professor) in all areas of statistics or econometrics to begin in the fall of 2012. Salary and benefits are competitive and commensurate with qualifications and experience.
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<td>ICSA c/o Shuyen Ho, Statistics and Programming GSK, GlaxoSmithKline, 5 Moore Drive, PO Box 13398, Research Triangle Park, NC 27709, USA</td>
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The First Joint Conference
by the
International Chinese Statistical Association (ICSA)
and the
International Society for Biopharmaceutical Statistics (ISBS)

Sunday, June 9 to Wednesday, June 12, 2013
Bethesda, Maryland, USA

The 22nd Annual ICSA Applied Statistical Symposium and the 3rd ISBS International Symposium on Biopharmaceutical Statistics will be held jointly from Sunday, June 9 to Wednesday, June 12, 2013, at the Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, Maryland, USA. We envision that this joint meeting will allow us to attract industrial statisticians and many international statisticians as well as statisticians working in government and academia.

There will be keynote speeches, short courses, invited sessions and contributed sessions. Details will be announced on our website http://www.icsa.org/2013/ and http://www.isbiostat.org/main/.

We at ICSA and ISBS join the strengths and efforts to make this conference a unique and memorable learning experience. We sincerely welcome all ICSA and ISBS members, and all people interested in application of statistics to participate, organize invited sessions, submit papers to the contributed sessions, and provide suggestions. The executive committee welcomes suggestions and help from all interested members. Questions and suggestions can be addressed to Aiyi Liu at liua@mail.nih.gov or Mark Chang at mchang@amagpharma.com.

The Executive Committee for 2013 ICSA-ISBS Joint Statistical Symposium