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## **Experience**

Dr. Colleen Kelly has over 25 years of statistical consulting experience in both industry and academic settings in a wide variety of subject areas. She has extensive experience in statistical consulting and data analysis for observational studies, clinical trials and other experiments and sample surveys. She has designed studies, analyzed data, written statistical analysis plans and reports in the oncology, pharmaceutical, vaccine and medical device and diagnostics arenas. She has helped medical device, diagnostic and pharmaceutical companies file and defend FDA submissions. Additionally, she has served as an expert witness in civil cases involving medical devices, intellectual property, antitrust, construction defects, and employee compensation. She has served as the lead statistician on several NIH and NSF grants.

As a tenured associate professor of statistics at San Diego State University, Dr. Kelly co-founded and co-directed the university's statistical consulting center. At Victoria University in Wellington, New Zealand, she directed the university's statistical consulting center, providing advice and data analysis for university researchers and the Ministry of Health. At Exponent Inc., she provided statistical consulting services to industry and legal clients. At Moores UCSD Cancer Center, she consulted with oncology researchers to efficiently and effectively design pre-clinical, and Phase I, II and III clinical trials and analyzed data from these experiments.

Dr. Kelly's research is primarily focused in biostatistics, developing statistical methodology to address biological and medical problems. She has developed and evaluated methodology for identifying drug interactions, and analyzing data from clinical trials and epidemiological, ecological, and behavioral studies. She has also worked in the area of modeling molecular evolution.

## **Employment**

President, Kelly Statistical Consulting (2009 – present)

Visiting Lecturer, Department of Mathematics, Computer Science and Statistics, Victoria University of Wellington, New Zealand (2015, 2016)

Principal Statistician, Moores UCSD Cancer Center, La Jolla (2009 – 2010)

Managing Scientist, Exponent Inc., Irvine (2007-2009)

Consulting Statistician, Department of Mathematics, Computer Science and Statistics, Victoria University of Wellington, New Zealand (2005–2007)

Associate Professor, Department of Mathematics and Statistics, San Diego State University (1997–2005)

Adjunct Associate Professor, Graduate School of Public Health, San Diego State University (1998–2005)

Assistant Professor, Department of Computer Sciences and Statistics, University of Rhode Island (1991–1997)

Research Assistant, Lab for Math and Statistics, UCSD (1986-1991)

### Academic Credentials and Professional Honors

Ph.D., Mathematics, University of California, San Diego 1991  
 M.S., Applied Mathematics, University of California, San Diego, 1988  
 B.A., Applied Mathematics, University of California, San Diego, 1986  
 PStat® Accredited Professional Statistician, American Statistical Association 2011  
 PStat® Accreditation Committee Review Member, 2015-2017  
 President of the San Diego Chapter of the American Statistical Association 2011-2013  
 Vice-President of the San Diego Chapter of the American Statistical Association 1999-2001, 2007-2009  
 Treasurer of the American Statistical Association Section on Medical Devices and Diagnostics, 2014-2016  
 TRW's Excellence in Teaching Award 2000  
 San Diego Chapter of the American Statistical Association Distinguished Service Award 2001, 2010  
 American Statistical Association Chapter Service Recognition Award 2002

### Publications

Quintos A, Naranjo M, Kelly C, Quan S, Sharma S. Recognition and treatment of sleep-disordered breathing in obese African American hospitalized patients may improve outcome. *Journal of the National Medical Association* 2018.

Yamamoto C, Sharma K, Henry R, Murakami T, Oakes M, Mitsuhashi M, Kelly C. Uromodulin mRNA from urinary extracellular vesicles correlate to kidney function decline in type 2 diabetes mellitus. *American Journal of Nephrology* 2018.

Malhotra A, Crocker ME, Willes L, Kelly C, Lynch S, Benjafield AV. Patient engagement using new technology to improve adherence to positive airway pressure therapy: a retrospective analysis. *CHEST* 2018; 153(4): 843:850.

Hwang D, Chang JW, Benjafield AV, Crocker ME, Kelly C, Becker KA, Kim JB, Woodrum RR, Liang J, Derose SF. Effect of telemedicine education and telemonitoring on CPAP adherence: the Tele-OSA randomized trial. *American Journal of Respiratory and Critical Care Medicine* 2018; 197(1):117-126.

Sharma S, Mukhtar U, Kelly C, Mather P, Quan SF. Recognition and treatment of sleep disordered breathing in obese hospitalized patients may improve survival. The HoSMed database. *American Journal of Medicine* 2017; 130: 1184-1191.

Scholz M, Yep S, Chancey M, Kelly C, Chau K, Turner J, Lam R, Drake C. Phase I clinical trial of sipuleucel-T combined with escalating doses of ipilimumab in progressive metastatic castrate-resistant prostate cancer. *ImmunoTargets and Therapy* 2017; 6: 1-6.

Apfel C, Jahr J, Kelly C, Ang R, Oderda G. Effect of i.v. acetaminophen on total hip or knee replacement surgery: a case-matched evaluation of a national patient database. *American Journal of Health-System Pharmacy* 2015; 72: 1961-8.

Zannolli R, Buoni S, Betti G, Salvucci S, Plebani A, Soresina A, Pietrogrande MC, Martino S, Leuzzi V, Finocchi A, Micheli R, Rossi LN, Brusco A, Misiani F, Fois A, Hayek J, Kelly C, Chessa L. A randomized trial of oral betamethasone to reduce ataxia symptoms in ataxia telangiectasia. *Movement Disorders* 2012; 27:1312-1316.

Kelly C, Feng P, Kawashima T, Wilmes A, Miller J. Two-stage model-free tests of synergy in drug combinations. *Journal of Biopharmaceutical Statistics* 2012; 22:54-71.

Sadler GR, Ko CM, Wu P, Alisangco J, Castañeda SF, Kelly C. A cluster randomized controlled trial to increase breast cancer screening among African American women: the black cosmetologists promoting health program. *Journal of the National Medical Association* 2011; 103:735-45.

Zhang L, Murray F, Rassenti L, Pu M, Kelly C, Kanter J, Greaves A, Messer K, Kipps T, Insel P. Cyclic nucleotide phosphodiesterase 7B mRNA: an unfavorable characteristic in chronic lymphocytic leukemia. *International Journal of Cancer* 2011; 129(5):1162-9.

- DeMoor P, Matusov Y, Kelly C, Kolan S, Barnachea L, Bazhenova L. A retrospective review of the frequency and nature of acute hypersensitivity reactions at a medium sized infusion center. *Journal of Cancer*. 2011; 2:153-164.
- Kelsh M, Berman W, Kelly C, Lau E, Lundin J, Mowat F. Naturally occurring asbestos and mesothelioma in California: is there a link? Sensitivity analyses of a recent ecologic study. Technical Report 2009.
- Wiener GJ, Tsukashima R, Kelly C, Wolf E, Schmeltzer M, Bankert C, Fisk L, Vaezi M. Oropharyngeal pH monitoring for the detection of liquid and aerosolized supraesophageal gastric reflux. *Journal of Voice* 2009;23(4):498-504.
- Kelly C, Arnold R, Galloway Y, O'Hallahan, J. THE AUTHORS REPLY. *American Journal of Epidemiology* 2008;167:1141-1142.
- Ray R, Ketcham B, Huang S-W, and Kelly C. Fire in large truck crashes: comparing results from the Large Truck Crash Causation Study with FARS and NASS/GES data, SAE 2008-02-0255.
- Wilmes A, Bargh K, Kelly C, Northcote P, Miller J. Peloruside A synergizes with other microtubule stabilizing agents in cultured cancer cell lines. *Molecular Pharmaceutics* 2007;4(2):269-280.
- Kelly C, Arnold R, Galloway Y, O'Hallahan, J. A prospective study of the effectiveness of the New Zealand meningococcal B vaccine (MeNZB™). *American Journal of Epidemiology* 2007;166(7):817-823.
- Chia S, Weisman RA, Tieu D, Kelly C, Dillmann WH, Orloff LA. Prospective study of perioperative factors predicting hypocalcemia after thyroid and parathyroid surgery. *Archives of Otolaryngology – Head & Neck Surgery* 2006;132(1):41–45.
- Kelly C, Price T. Correcting for regression to the mean in behavior and ecology. *American Naturalist* 2005; 166(6):700–707.
- Kelly C, Rao-Melacini P, Zhao W. Using James-Stein estimators in tests of homogeneity of the risk difference. *Communications in Statistics – Simulation and Computation* 2005;34(1): 41–55.
- Feng P, Kelly C. An extension of the Model-Free Test to test synergy in multiple drug combinations. *Biometrical Journal* 2004;3:293–304.
- Romano TA, Keogh MJ, Kelly C, Feng P, Berk L, Schlundt CE, Carder DA, Finneran J. Anthropogenic sound and marine mammal health: measures of the nervous and immune systems before and after sound loud enough to shift hearing threshold. *Canadian Journal of Fisheries and Aquatic Sciences* 2004;61:1124–1134.
- Kelly C, Price T. Comparative methods based on species mean values, *Mathematical Biosciences* 2004;187(2): 135–154.
- Smith J, Kelly C. Stylistic constancy and change across literary corpora: using measures of lexical richness to date works. *Computers and the Humanities* 2002;36(4):411–430.
- Lui K-J, Kelly C. Tests for homogeneity of the risk ratio in a series of 2x2 tables. *Statistics in Medicine* 2000; 19(21):2919–2932.
- Castillo EM, Rickman LS, Ledbetter EL, Kelly C. *Streptococcus Pneumoniae* bacteremia in an era of penicillin resistance. *American Journal of Infection Control* 2000;28(3):239–243.
- Lui K-J, Kelly C. A revisit of tests for homogeneity of the risk difference. *Biometrics* 2000; 56:309–315.
- Kelly C, Lake S, Mather T. Estimation of the transmission probability of Lyme borreliosis. *Biometrical Journal* 1999;41(6):1–17.
- Lui K-J, Kelly C. A note on interval estimation of kappa in a series of 2x2 tables. *Statistics in Medicine* 1999; 18:2041–2049.
- Kelly C, Kammann E, Bak J, Mather T. An improved method for predicting duration of black-legged tick (*Ixodes scapularis*) attachment. *Systematic and Applied Acarology* 1999;4:31–38.
- Legare ML, Eddleman WR, Buckley PA, Kelly C. The effectiveness of tape playback in estimating Black Rail density. *Journal of Wildlife Management* 1999;63(1):116–125.
- Hu R, Markowski D, Hyland K, Kelly C, Mather T. Human Infection with tick-transmitted *Babesia microti* in Rhode Island: serological evidence and risk factor assessment. *Journal of Spirochetal and Tick-borne Diseases* 1996;3(3):135–139.

- Kelly C, Churchill G. Biases in amino acid replacement matrices and alignment scores due to rate heterogeneity. *Journal of Computational Biology* 1996; 3(2):307–318.
- Kelly C, Rice J. Modeling nucleotide evolution: a heterogeneous rate analysis. *Mathematical Biosciences* 1996;133:85–109.
- Yeh M-T, Bak JM, Hu R, Nicholson M, Kelly C, Mather T. Determining the duration of *Ixodes scapularis* attachment to tick-bite victims, *Journal of Medical Entomology* 1995;32(6):853-8.
- Kelly C. A test of the Markovian model of DNA evolution. *Biometrics* 1994;50:653–664.
- Kelly C, Rice J. Monotone smoothing and its application to dose-response curves and the assessment of synergy. *Biometrics* 1990;46:1071–1085.
- Goel R, Cleary SM, Horton C, Kirmani S, Abramson I, Kelly C, Howell SB. Effect of sodium thiosulfate on the pharmacokinetics and toxicity of cisplatin. *Journal of the National Cancer Institute* 1989;81(20):1552–1560.

### Published Presentation Proceedings

- Miller J, Wilmes A, Bargh K, Kelly C, Northcote P. Peloruside A and paclitaxel synergise in their cytotoxic and microtubule-stabilizing effects in cultured cancer cell lines. 97<sup>th</sup> Annual Meeting of the American Association for Cancer Research 2006, Washington D.C., April 1–4, 2006.
- Wiener GJ, Bankert C, Kelly C, Fisk CL, Schmeltzer M, Wolf E, Tsukashima R. Dx-1: A new device for detecting supraesophageal gastric reflux (SEGR). American College of Gastroenterology's 70<sup>th</sup> Annual Meeting, Honolulu, Hawaii (abstract), 2005.
- Oechel WC, DeRoma D, Ross D, Taylor N, Kelly C, Verfaillie J. Using near-real-time data in K-6 educational outreach. American Meteorological Society's 14<sup>th</sup> Symposium on Education (abstract), 2004.
- Lo K, Kelly C. A bootstrap test for homogeneity of risk differences in a matched-pairs, multi-center design. Proceedings, American Statistical Association, Biopharmaceutical Section, Toronto, Canada, 2004.
- Rao-Melacini P, Kelly C. The use of James-Stein estimators in tests of homogeneity of the risk difference. Proceedings, American Statistical Association, Biopharmaceutical Section, Toronto, Canada, 2004.
- Feng P, Kelly C. An extension of the MFT to test synergy in multiple drug combinations. Proceedings, American Statistical Association, Biometrics Section, San Francisco, CA, 2003.
- Kelly C, Kawashima T, Feng P. An improved Model-Free Test of synergy in drug combinations. Proceedings, American Statistical Association, Biometrics Section, San Francisco, CA, 2003.
- Kelly C. Heterogeneous rate models of DNA evolution. Proceedings, American Statistical Association, Biometrics Section, Chicago, IL, pp. 189–193, 1996.

### Additional Selected Abstracts and Presentations

- Chancey, M, Yep S, De Guzman K, Kelly C, Scholz M. Phase I Sipuleucel-T combined with escalating doses of Ipilimumab (SIPITI) in progressive mCRPC. ASCO Cancer Survivorship Symposium, January 2017.
- Kelly C. Statistical issues in trademark dilution and infringement. Joint Statistical Meetings, Section on Statistical Consulting, Denver, CO, August 2008.
- Kelly C. Analysis of Quantitative Data Workshop. Office of Research and Postgraduate Studies, Victoria University, New Zealand, March 2007.
- Kelly C. Quantitative Research Design Workshop, Office of Research and Postgraduate Studies, Victoria University, New Zealand, February 2006.
- Kelly C. A Crash Course in Designing Comparative Studies. Office of Research and Postgraduate Studies, Victoria University, New Zealand, November 2005.
- Kelly C, Steffey D. Statistical consulting at SDSU: Meeting the needs of students and clients. 5<sup>th</sup> Annual Workshop on Statistical Consulting and Collaboration, Claremont, CA, November 15, 2003.

**Peer Reviewer**

*Journal of Biopharmaceutical Statistics*  
*Statistics in Biopharmaceutical Research*  
*Journal of Clinical Oncology*  
*Biometrics*  
*Mathematical Biosciences*  
*Clinical Research and Regulatory Affairs*  
*Freeman*  
*Prentice Hall*

*Contemporary Clinical Trials*  
*PLOS One*  
*Journal of Computational Biology*  
*Journal of Theoretical Biology*  
*Theoretical Population Biology*  
*Duxbury Press*  
*Wm. C. Brown Publishers*

**Service for the professional community:**

- Organizer, Pacific Coast Statisticians and Pharmacometricians Innovation Conference, San Luis Obispo (2012, 2014).
- Treasurer, American Statistical Association Section on Medical Devices and Diagnostics (2014-2016).
- President, San Diego Chapter, American Statistical Association (2011-2013).
- American Statistical Association, Professional Statistician Accreditation Review Board (2015-2017).
- Vice President of Professional Affairs, San Diego Chapter, American Statistical Association (2007-2009).
- Vice President of Academic Affairs, San Diego Chapter, American Statistical Association (1999-2001).
- Organizer of SDSU's Statistical Career Day (2000, 2001, 2008), Biostatistics/Statistics Career Lunch (1999), Orientation for Graduate Statistics Students (1998, 2000, 2001, 2002), the Graduate Student Social (1999) and the ASA dinner seminar Current Statistical Issues in San Diego (1999).
- Science Judge at the Greater San Diego Science Fair (1999, 2008).
- Event Chair of Practical Data Gathering Science Olympiads (2002-2004).