

Contact Information

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Employment History

University of Virginia / Biocomplexity Institute & Initiative / Social and Decision Analytics Division (SDAD)

10/15/2018 to present: Principal Scientist
1100 Wilson Blvd., Arlington, VA 22209

Virginia Tech / Biocomplexity Institute / Social Decision and Analytics Lab (SDAL)

12/10/2015 to 10/12/18: Senior Research Scientist
SDAL/BI/VA Tech
900 North Glebe Road
Arlington, VA 22203

Food and Drug Administration / Center for Drug Evaluation and Research

05/18/2013 to 12/10/2015: Mathematical Statistician
FDA/CDER/OTS/OB/DBVI
10903 New Hampshire Avenue, BLDG 21
Silver Springs, MD 20852

Food and Drug Administration / Center for Tobacco Products

01/15/2012 to 05/17/2013: Mathematical Statistician
FDA/CTP/OS
10903 New Hampshire Avenue, BLDG 75
Silver Springs, MD 20852

Food and Drug Administration / Center for Veterinary Medicine

6/21/2009 to 01/14/2012: Mathematical Statistician
FDA/CVM/ONADE/DSS
7519 Standish Place
Rockville, MD 20855

Neptune and Company, Inc.

8/15/1997 to 1/15/2009: Senior Statistician
Neptune and Company, Inc.
1505 15th Street, Suite B
Los Alamos, NM 87544

Kansas State University

1990 to 1994: Graduate Research Assistant, Department of Statistics

1989 to 1990: Graduate Teaching Assistant, Department of Statistics

Statistical Resources, Inc.

1988 to 1989: Statistician

Louisiana State University

1987 to 1988: Statistical Research Associate, Department of Zoology and Physiology

1983 to 1987: Graduate Teaching Assistance, Department of Statistic

Education and Training

B.S. Areas of concentration: Chemistry and Russian Studies. Louisiana State University, 1979.

M.S. Statistics with a Minor in Mathematics. Louisiana State University, 1988.

Ph.D. Statistics. Kansas State University, 1997.

Professional Experience

SDAD: Work with an interdisciplinary team of researchers from the social sciences focused on leveraging the data revolution to address the social and public good.

Prior to SDAD: Collaborate with scientists and engineers from the life and physical sciences on the statistical design of experiments, the collection, analysis, and interpretation of data, and the writing and review of technical documents.

Data Analysis and Interpretation

UVA/SDAD: Constructed the computer laboratory experimental design and conducted the statistical analysis for the Minerva Project. The design explored human decision-making by controlling for network structure and messaging conditions, on coordination in threshold participation games under global and local network information.

VA Tech/SDAL: Worked with coordinated teams of researchers to address complex social problems with multiple cause-effect relationships such as: military attrition and performance, school dropout, decision making in post-secondary education, mass transit fare evasion, coordination in threshold participation games, and identifying vulnerable populations. Contributions included novel application of statistical methods and graphical displays, and method development in the area of the statistical properties of composite indicators.

FDA/Center for Drug Evaluation and Research: Worked in the Office of Biostatistics on issues related to generic drugs. This included providing statistical expertise to the Office of Research and Standards within the Office of Generic Drugs. Consulting projects included: designing experiments to evaluate the in-vitro/in-vivo correlation of parental microsphere ocular drug products, developing a one-sided inferential test to evaluate population bioequivalence for the drug in small particles/droplets by cascade impactor test, exploratory data analysis of the distribution of peptide copolymers in the multiple sclerosis drug glatiramer acetate, and evaluating and developing inferential methods for the noninferiority comparison of reference and generic transdermals for highly skewed distributions.

FDA/Center for Tobacco Products: Worked in collaboration with CTP chemists in the Office of Science as the sole statistician conducting exploratory data analyses on the harmful and potentially harmful constituents, product design, and composition of the 50 U.S. top selling cigarettes. This work resulted in two seminal papers with CDC on the relationship between nicotine, tar, and carbon monoxide, and cigarette product design.

Was the sole statistician analyzing the ingredient data base (Section 905^a of the Family Smoking Prevention and Tobacco Control Act requires establishment registration and product listing by manufacturers, and Section 904(a)(1) requires the listing of ingredients of tobacco products by manufacturers and importers of tobacco products). Worked with toxicologists on risk models for smokers using smoking topography distributions.

One of a team of statisticians who developed the Population Assessment of Tobacco Health (PATH) survey; a nationally representative longitudinal cohort study of approximately 59,000 non-tobacco and tobacco users. The PATH study is designed to provide an evidence base for assessing and monitoring FDA's current and future regulatory actions.

^a 21 U.S.C. 387e.

FDA/Center for Veterinary Medicine: Worked in collaboration with scientists at the Office of Research (OR) as the sole statistician on investigations into screening test kits, bridging studies, depletion studies, residues in animal food products, antimicrobial resistance, genomic and proteomic biomarker discovery. Worked in collaboration with scientists at the Office of New Animal Drug Evaluation (ONADE) and the University of Maryland School of Pharmacy on investigations into the process and formulation variables used in the tablet manufacturing process.

Developed novel visualization and simulation methods to provide veterinary reviewers with insights into the data from drug applications. Lead the Target Animal Safety Focus group to construct an approach to data interpretation that incorporated a multivariate approach using both visualization and inferential analyses.

Was the sole statistician on the CVM research team evaluating inorganic arsenic in poultry. Constructed the experimental design, analyzed and interpreted the data that lead to the FDA finding that roxarsone (an organoarsenic compound used by producers to increase weight gain) is associated with elevated levels of inorganic arsenic in chicken livers. As a consequence, in July of 2011 Pfizer suspended its sale of roxarsone.

Neptune and Company, Inc.: Wrote S-PLUS and R code to implement the most current statistical techniques for environmental data analysis. Performed comprehensive statistical analyses and data quality assessments of data sets in support of remedial decision-making and a large groundwater data set pertaining to a complex DoD site.

Under Contract to the EPA National Risk Management Research Laboratory (NRMRL): Consulted with numerous NRMRL scientists on issues pertaining to experimental design, sampling design, model construction and validation, data analysis and interpretation, and the presentation of statistical results.

Under Contract to the USDA Agricultural Research Service (ARS): Consulted with numerous ARS scientists on statistical issues pertaining to experimental design, sampling design, data analysis and interpretation, model construction and validation, and the presentation of statistical results.

Kansas State University: Assisted in analyzing pharmaceutical efficacy data. The data were provided by industry for contract work at Kansas State University.

Statistical Resources Inc.: Analyzed data from chemical and psychological studies. Wrote data manipulation/statistical algorithms in C to interface with a near infrared refractometer.

Louisiana State University: Served as the consulting statistician for a department of approximately 50 faculty and students. Consultations included questions concerning the design, analysis, interpretation, and presentation of biological experiments in the areas of quantitative/ behavioral genetics and physiology.

Training

FDA/Center for Tobacco Products: Developed and taught workshops on data visualization and data analysis using the freeware statistical and graphical software R.

FDA/Center for Veterinary Medicine: Developed and taught three sections of an R workshop for statistical computing and graphics at the Learning Management Institute.

Under Contract to the EPA National Risk Management Research Laboratory (NRMRL): Managed workshops on environmental statistics whose topics included sampling design, multivariate analysis of variance, exploratory data analysis, and nonlinear models. Taught numerous workshops on topics such as experimental design, model comparison techniques, analysis of variance, multivariate analysis of variance, quasi-experimental design, logistic regression, time series, and the analysis and interpretation of data from Superfund Innovative Technology Evaluation (SITE) demonstrations.

Under Contract to the USDA Agricultural Research Service (ARS): Developed a series of twelve-four hour statistical workshops. Wrote the standalone workbooks that accompanied each workshop. Eight workshops were taught in a computer laboratory where all statistical methods discussed were implemented in SAS Analyst. Wrote a separate book on SAS Analyst to accompany the workshops. Three spatial workshops were taught in computer laboratories using the freeware R, one workshop dealt with how to use R. The workshops

were conducted at a facility so participants at remote locations could attend and participate in the workshop and/or conducted over the internet.

Kansas State University: Taught a biometrics course for two semesters to undergraduate students at the sophomore level.

Louisiana State University: Taught several semesters of statistical laboratories for graduate and undergraduate level courses for the computer implementation of statistical methodologies.

Quality Assurance

FDA/Center for Drug Evaluation and Research: Worked in the Office of Biostatistics on issues related to generic drugs. This included writing the statistical sections of Bioequivalence Guidances for industry, reviewing Abbreviated New Drug Applications (ANDAs) for statistical accuracy, and reviewing the work of other statisticians for technical and editorial accuracy. Developed templates for filing reviews of pre-submission ANDAs used by all statistical reviewers. Reviewed all statistical filing reviews for technical and editorial accuracy.

Wrote the statistical sections of drug specific bioequivalence guidances on used by industry for the submission of generic drug applications. Currently working on a guidance for the in-vitro testing of generic opioids, "General Principles for Evaluating Abuse-Deterrent Properties of Generic Solid Oral Opioid Drug Products", and a guidance for the clinical evaluation of transdermal products for adhesion, "Assessing Adhesion with Transdermal Delivery Systems."

FDA/Center for Tobacco Products: Helped to develop statistical guidance for the review of investigational tobacco product risk and exposure modification studies. Developed a presentation to CTP scientists on how statistical logic can be used to access and quantify "substantial equivalence." Provided the first statistical review for an application to introduce an investigational cigarette product.

FDA/Center for Veterinary Medicine: Reviewed technical documents such as protocols and final study reports dealing with efficacy and target animal safety. As a consulting reviewer for the ONADE, evaluated these documents for concurrence of the statistical approach and when a nonoccurrence was issued provided a detailed discussion on how to bring the submission into concurrence.

Neptune and Company, Inc.: Reviewed and wrote technical documents pertaining to site characterization. Reviewed project reports to determine adequacy of statistical approach. Conducted research to evaluate the performance and use of composite sampling schemes, as well as the performance and use of bootstrap confidence and tolerance levels for lognormal distributions.

Under Contract to the EPA National Risk Management Research Laboratory (NRMRL): Reviewed technical documents such as Quality Assurance Project Plans, Technical Evaluation Reports, Sampling and Analysis Plans, and journal articles.

Under Contract to the Parsons-UXB Joint Venture Kaho`olawe Unexploded Ordnance (UXO) Clearance Project: Reviewed the UXO detection and removal process, and the data collection, transfer, and storage process for completeness and accuracy. Estimated the UXO clearance effectiveness in the Lua Makika work area and predicted the number of UXO remaining.

Under Contract to Earth Tech, Inc. Former Camp Beale Site Investigation: Reviewed the UXO detection and removal process, and data collection, transfer, and storage process for completeness and accuracy. Employed a novel approach to identify target areas. Model based clustering and local regression methods were used to identify open burn/open detonation areas that posed the highest risk to the public and landowners.

Project Planning and Facilitation

UVA/SDAD: SDAD lead on two cooperative agreements with the NSF/NCSES on the Skilled Technical Workforce and NCSES Visualizations.

VA Tech/SDAL: Facilitated the literature searches for two Army Research Institute grants on the social component of the human dimension and enlisted attrition. The goals of the literature reviews were to:

identify new ways to interpret the literature, identify potential data sources, identify areas of prior scholarship to prevent duplication of effort, reveal knowledge gaps, locate our research within the context of the existing literature, and identify areas for additional research.

Under Contract to Research Triangle Institute International (RTI): Assisted EPA, Office of Air Quality Planning and Standards, in revising the lead National Ambient Air Quality Standards (NAAQS) monitoring requirements. Evaluated scenarios to determine the effect of alternative sampling frequencies and hypothetically achieved data quality indicators (precision, bias, and completeness relative to the required schedule) on the precision with which comparisons of ambient lead concentrations can be made to the lead NAAQS. Bootstrapping was used to develop the population model that was then used to test different forms of the decision rule. This task also included: statistical support to evaluate alternative completeness requirements to determine how often these alternative completeness requirements result in the right attainment decision and how often the completeness requirements would result in the wrong attainment decision; statistical support to evaluate alternative requirements for the development of site specific scaling factors relating collocated Pb-TSP and Pb-PM10 measurements.

Under Contract to the EPA National Homeland Security Research Center (NHSRC): Assisted in the development of a detection system for biological contaminants in the nation's water supply by constructing the experimental design for an inter-laboratory investigation for newly developed ultrafiltration and analytic methods for various biological contaminants.

Kansas State University: Supported the Environmental Restoration Program at Los Alamos National Laboratory in the areas of instrument calibration, kriging, risk analyses, detection limits, left censored data, and environmental sampling.

FDA Awards

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| 2010 | Outstanding New Reviewer |
| 2011 | Excellence in Analytical Science Group Award as a member of the Replacement of Obsolete Penicillin Method Team |
| 2013 | Excellence in Analytical Science Group Award as a member of the Ceftiofur Bridging Team |

Peer Reviewed Publications

Woteki CE, Kramer, BL, Cohen S, Lancaster VA. **Impacts and Echoes: The Lasting Influence of the White House Conference on Food, Nutrition and Health.** *Annual Review* (In Press).

Lancaster VA. **What the Adult Training and Education Survey Tells Us About the Skilled Technical Workforce.** (In Review).

Lancaster VA, Mahoney-Mair D, Ratcliff NJ. **Technology Report: Review of Burning Glass Job-ad Data.** (In Review).

Pires B, Crandell I, Arnsberger A, Lancaster V, Keller S, Schroeder A, Shipp S, Kang W, Robinson P. **Predicting Postsecondary Trajectories in Virginia High Schools using Publicly Available Data.** *Journal of the IOAS*, 2018 34(4):553-565.

Keller S, Shipp S, Korkmaz G, Molfino E, Goldstein, J, Lancaster V, Pires B, Higdon D, Chen D, Schroeder A. **Harnessing the power of data to support community-based research.** *WIREs Computational Statistics*, 2018 doi: 10.1002/wics.1426.

Ziemer KS, Pires B, Lancaster V, Keller S, Orr M, Shipp S. **A New Lens on High School Dropout: Use of Correspondence Analysis and the Statewide Longitudinal Data System.** *The American Statistician*, 2018 72(2):191-8.

Keller SA, Lancaster V, Shipp, S. **Building Capacity for Data Driven Governance - Creating a New Foundation for Democracy.** *Statistics and Public Policy*, 2017 4(1):1-11.

<http://amstat.tandfonline.com/doi/full/10.1080/2330443X.2017.1374897#.WbcHY9OGOqA>

Agnew-Heard KA, Lancaster VA, Bravo R, Watson C, Walters MJ, Holman MR. **Multivariate Statistical Analysis of Cigarette Design Features Influence on CAN TNCO Yields.** *Chemical Research Toxicology*, 2016 Jun;29(6):1051-63.

Swain MD, Orzechowski KL, Swaim HL, Jones YL, Robi MG, Tinaza CA, Myers MJ, Jhingory MV, Buckely LE, Lancaster VA, Yancy HF. **P-gp Substrate-Induced Neurotoxicity in an Abcb1a Knock-in/Abcb1b Knock-out mouse model with a mutated canine ABCB1 targeted insertion.** *Research in Veterinary Science*, 2012 Nov;94(3).

Chiesa OA, Li H, Kijak PJ, Li XJ, Lancaster VA, Smith ML, Heller DN, Thomas MH, Von Bredow J. **Tissue/Fluid Correlation Study for the Depletion of Sulfadimethoxine in Bovine Kidney, Liver Plasma, Urine, and Oral Fluid.** *Journal of Veterinary Pharmacology & Therapeutics*. 2012 Jun;35(3):249-58. DOI: <http://dx.doi.org/10.1111/j.1365-2885.2011.01327.x>. Epub 2011 PMID:21831115.

Boehmer JL, Degrasse JA, Lancaster VA, McFarland MA, Callahan JH, Ward JL. **Evaluation of protein expression in bovine bronchoalveolar fluid following challenge with Mannheimia haemolytica.** *Proteomics*. 2011 Sep;11(18):3685-97. DOI: <http://dx.doi.org/10.1002/pmic.201000710>.

Rinderer TE, Blum MS, Fales HM, Bain S, Jones TH, Bucu SM, Lancaster VA, Danka RD, Howard DF. **Nest Plundering Allomones of the Fire Bee Trigona (Oxytrigona) Mellicolor.** *Journal of Chemical Ecology*. 1982 Feb;14(2):495-501.

Rinderer TE, Collins AM, Pesante D, Daniel R, Lancaster VA, Baxter J. **A Comparison of Africanized and European Drones: Weights, Mucus Gland and Seminal Vesicle Weights, and Counts of Spermatozoa.** *Apidologie*, 1985 Jan;16:407-12

Rinderer TE, Sylvester, HA, Brown MA, Villa JD, Pesante D, Collins AM, Spencer R, Kleinpeter S, Lancaster VA. **Field and Simplified Technique for identifying Africanized and European Honey Bees.** *Apidologie*, 1986 Jan;17(1).

Bucu SM, Rinderer TE, Sylvester HA, Collins AM, Lancaster VA, Crewe R. 1987. **Morphometric differences between South American Africanized and South African (Apis mellifera L. Scutellata) honey bees.** *Apidologie*, 1987 Jan;18(3):217-222.

Rinderer TE, Sylvester, HA, Bucu SM, Lancaster VA, Herbert EW, Collins AM, Hellmich, RL. 1987. **Improved Simple Technique for Identifying Africanized and European Honey Bees.** *Apidologie*, 1987 Jan;18(2): 179-196.

De Guzman LI, Rinderer TE, Lancaster VA. **A Short Test Evaluating Larval Attractiveness of Honey Bees to Varroa jacobsoni Oudemans (Acari: Varroidae).** *Journal of Apicultural Research*, 1995;34:89-92

Lancaster VA, Keller-McNulty S. **How well does composite sampling work for spatial site characterization?** *Environmental Testing and Analysis*, 1998;7(5):14-15, 29.

Lancaster VA, Keller-McNulty S. **An Application of Composite Sampling.** *Environmental Testing and Analysis*, 1998;7(4): 15,16,18, 32.

Lancaster VA, Keller-McNulty S. 1998. **A Review of Composite Sampling Methods.** *Journal of the American Statistical Association*, 1998;93(443): 116-123.

Sinacori A, Rinderer TE, Lancaster VA, Sheppard WS. **A Morphological and Mitochondrial Assessment of APis Melifera from Palermo, Italy.** *Apidologie*, 1998 Nov;29(6):481-90.

Rinderer TE, De Guzman LI, Lancaster VA, Delatte GT, Stelzer JA. **Varroa in the Mating Yard: I. The Effects of Varroa jacobsoni and Apistan (R) on Drone Honey Bees,** *American Bee Journal*, 1999;139:134-9.

Rinderer TE, De Guzman LI, Delatte GT, Stelzer JA, Lancaster VA, Kuznetsov V, Bearman L, Watts R, Harris J. **Resistance to the Parasitic Mite Varroa Destructor in Honey Bees from Far-Eastern Russia.** *Apidologie*, 2001 July;32(4) :381-94.

Rinderer TE, De Guzman LI, Delatte GT, Stelzer JA, Lancaster VA, Williams JL, Beaman GD, Kuznetsov V, Bigalk M, Bernard SJ. **Multi-State Field Trials of ARS Russian Honey Bees #2, Honey Production 1999, 2000.** *American Bee Journal*, 2001 Oct;141(10): 726-29.

Beaulieu JC and Lancaster VA. **Correlating Volatile Compounds, Sensory Attributes, and Quality Parameters in Stored Fresh-Cut Cantaloupe.** *Journal of Agricultural and Food Chemistry*, 2007 Dec;55(23):9503:13.

Vega AM, Lancaster VA, Roulier MH. **Comparison of Two Field Sampling Procedures (En Core and Field Methanol Extraction) for Volatile Organic Compounds.** *Environmental Science and Technology*, 2005 Jan;38(24):6790-4.

Feng S, Chiesa OA, Kijak PJ, Chattopadhyaya C, Lancaster VA, Smith EA, Girard L, Sklenka S, Li, H. **Determination of Ceftiofur Metabolite Desfuroylceftiofur Cysteine Disulfide in Bovine Tissues Using Liquid Chromatography Tandem Mass Spectrometry as a Surrogate Marker Residue for Ceftiofur.** *Journal of Agriculture and Food Chemistry*. 2014 May;62(22). DOI: <http://pubs.acs.org/articlesonrequest/AOR-mqAnZzXusrtczH27tgSa>.

Swain MD, Orzechowski KL, Swaim HL, Jones YL, Robi MG, Tinaza CA, Myers MJ, Jhingory MV, Buckely LE, Lancaster VA, Yancy HF. **P-gp Substrate-Induced Neurotoxicity in an Abcb1a Knock-in/Abcb1b Knock-out mouse model with a mutated canine ABCB1 targeted insertion.** *Research in Veterinary Science*, 2012 Nov;94(3).

Peters SM, Yancy H, Deaver C, Jones YL, Kenyon E, Chiesa OA, Esparza J, Screven R, Lancaster VA, Stubbs III JT, Yang M, Wiesenfeld PL, Myers M. **In Vivo Characterization of Inflammatory Biomarkers in Swine and the Impact of Flunixin Meglumine Administration.** *Veterinary Immunology and Immunopathology*. 2012 May;148(3-4):236-42. DOI: <http://dx.doi.org/10.1016/j.vetimm.2012.05.001>.

Chiesa OA, Li H, Kijak PJ, Li XJ, Lancaster VA, Smith ML, Heller DN, Thomas MH, Von Bredow J. **Tissue/Fluid Correlation Study for the Depletion of Sulfadimethoxine in Bovine Kidney, Liver Plasma, Urine, and Oral Fluid.** *Journal of Veterinary Pharmacology & Therapeutics*. 2012 Jun;35(3):249-58. DOI: <http://dx.doi.org/10.1111/j.1365-2885.2011.01327.x>. Epub 2011 PMID:21831115.

Boehmer JL, Degrasse JA, Lancaster VA, McFarland MA, Callahan JH, Ward JL. **Evaluation of protein expression in bovine bronchoalveolar fluid following challenge with Mannheimia haemolytica.** *Proteomics*. 2011 Sep;11(18):3685-97. DOI: <http://dx.doi.org/10.1002/pmic.201000710>.

Agnew-Heard KA, Lancaster VA, Bravo R, Watson C, Walters MJ, Holman MR. **Multivariate Statistical Analysis of Cigarette Design Features Influence on CAN TNCO Yields.** *Chemical Research in Toxicology*, 2016, 29(6):1051-1063.

Federal Government Publications

3-Nitro (Roxarsone) and Chicken (Statistician's Report)

<http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/UCM257548.pdf>