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Chapter 1

ASA Competition (10)

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Sponsoring Section/Society: ASA-SBSS

Session Title: Bayesian Generalized Linear Models

The role of the statistician in public policy is to help stakeholders effectively use information and accurately quantify uncertainty when making decisions. This often requires blending of information from many samples or sites. This blending creates several problems: 1) the increased heterogeniety observed across samples is not accounted for using conventional models, 2) geographic correlation of samples may need to be incorporated, and 3) estimates may be needed at both local and global levels. Bayesian hierarchical models are especially well suited to solving these problem. In this session speakers will discuss how Bayesian Generalized Linear Models can be used to solve these problems using examples from environmental monitoring, geographic and temporal disease mapping, and risk assessment.

Session Organizer: **Sun, Dongchu** University of Missouri
Session Chair: **Speckman, Paul L.** University of Missouri-Columbia

1. Overdispersed Generalized Linear Models
Dey, Dipak, University of Connecticut

Abstract: Generalized linear models have become a standard class of models for data analysts. However in some applications, heterogeneity in samples is too great to be explained by the simple variance function implicit in such models. A two parameter exponential family which is overdispersed relative to a specified one parameter exponential family yields a the class of overdispersed generalized linear models (OGLM's) which are analytically attractive. We propose fitting such models within a Bayesian framework employing noninformative priors in order to let the data drive the inference. Hence our analysis approximates likelihood-based inference but provides an entire posterior distribution for model parameters. Bayesian calculations are carried out using a Metropolis sampling algorithm. An example involving damage *incidents to cargo ships motivates our work. Details of the data analysis are provided including comparison with the standard generalized linear models analysis. Several diagnostic tools reveal the improved performance of the OGLM.*

2. *Hierarchical and Empirical Bayes Methods for Environmental Risk Assessment*

Sankar, Gauri Sankar, University of Georgia
Ghosh, Malay, University of Florida
Waller, Lance, University of Minnesota

Abstract: The cancer and other disease atlases have become important tools for environmental monitoring and risk assessment. To study geographical variation in incidence of disease and mortality rates for local areas preparation of these maps has received considerable attention in recent years. Such maps usually display either relative rates in each area, as measured by a standardized mortality ratio (SMR), or p-values based on some statistical tests. None of these methods is entirely satisfactory. The raw SMR estimates are often based on small sample sizes, and hence are usually unreliable. In order to borrow strength from the local areas and to smooth the raw estimates a model-based procedure is often appropriate. We will review the recent developments in hierarchical Bayes generalized linear models including random effects for local areas. Both hierarchical and empirical Bayes estimation will be considered.

3. *Default Bayesian Analysis for Generalized Linear Model*

Sun, Dongchu, University of Missouri
Tsutakawa, Robert, University of Missouri

Abstract: Bayesian analysis for a generalized linear model, where the prior follows a hierarchical linear mixed model, has received much attention recently. In practice, it is often very difficult to choose the hyperparameters. This paper first gives necessary and sufficient conditions for the propriety of the posterior

distribution in hierarchical linear mixed effects models for a collection of improper prior distributions. In addition to the flat prior for the fixed effects, the collection includes various limiting forms of the invariant gamma distribution for the variance components, including cases considered previously by Datta and Ghosh (1991), Datta (1992), and Hobert and Casella (1996). Previous work is extended by considering a family of correlated random effects which include as special cases the CAR (1) models by Besag, York and Mollie (1991) and Clayton and Kaldor (1987) and autoregressive model by Ord (1975), which have been found useful in the analysis of spatial effects. A noninformative prior for the spatial correlation coefficients are also examined. Conditions are then presented for the propriety of the posterior distribution for generalized linear mixed models. The methods are successfully applied for estimating the mortality or disease rates including demographic variables such as age and sex, random geographic variables such as regional differences, longitudinal variables such as temporal trends in mortality, and spatial variables such as the correlation between neighboring regions.

Discussant: **Albert, Jim** Bowling Green State University

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Sponsoring Section/Society: ASA-SBSS

Session Title: Expected Utility Maximization and Simulation

The role of the statistician in public policy is to help stakeholders effectively use information to maximize utility when making decisions. This requires good research design, blending historical and current information, predicting future outcomes, conveying uncertainty associated with predictions, and incorporating results into a decision-theoretic framework. The Bayesian paradigm is especially suited to policy because its decision-theoretic focus is tailored to these requirements. In this session speakers will discuss theoretical frameworks, design, and computational issues pertinent to maximizing expected utility.

Session Organizer: **Peter Mueller** Duke University
Session Chair: **Peter Mueller** Duke University

1. Computational issues in Decision Analysis
Insua, David Rios, U. Juan Carlos, Madrid
Bielza, Concha, Universidad Politecnica de Madrid
Mueller, Peter, Duke University

Abstract: Most recent work in Bayesian computation have focused on Inference problems, with relatively little emphasis on Decision Theoretical problems. We shall describe some recent computational methods for Decision Analysis. Some of them will be MCMC based; others will be based on heuristics.

2. Backwards Induction, Direct Monte Carlo and Hybrid Methods of Computing Optimal (or very good) Designs
Kadane, Joseph B., Carnegie Mellon University

Abstract: Optimal designs can be computed analytically for only a few special cases. For Bayesian optimal designs to become *a serious practical method, computational methods are needed to address more general situations. This paper reviews some of the currently available methods, for both group-sequential and fixed-sample-size problems.*

3. Expected Utilities and Optimality Criteria in Bayesian Experimental Design. The Case of Unknown Variance

Verdinelli, Isa, Carnegie Mellon University

Abstract: This talk emphasizes the distinction between expected utility functions and optimality criteria in the Bayesian theory of experimental design. It also deals with the case of unknown variance when designing in the normal linear model structure.

Most of the Bayesian theory of optimal experimental design has been developed under the restrictive assumption of the model's variance being known. Insensitivity of specific design criteria to specific prior assumptions for the variance has been shown in special cases. The talk presents a general result that clarifies how most Bayesian optimal design criteria are not affected by information about data variability and proves that insensitivity of Bayesian design to information about the variance is quite general.

4. Valuation network representation of Bayesian decision problems

Shenoy, Prakash, University of Kansas

Abstract: I will describe the valuation network representation and solution of Bayesian decision problems. The valuation network representation emphasizes factorization of the joint probability distribution function and factorization of the joint utility function. A brief comparison with influence diagram representation and solution technique will be given.

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ASA Competition: Statistical Computing Section

Session Title: Smoothing Methods and Data Analysis

Session Organizer: **O'Connell, Michael** Becton Dickinson
Session Chair: **O'Connell, Michael** Becton Dickinson

1. ***When is a Feature Really There? The SiZer Approach***
Marron, J.S., University of North Carolina
Chaudhuri, Probal, Indian Statistical Institute

Abstract: When applying smoothing methods to data, the central question is often "which observed features are part of the true underlying curve, and which are spurious sampling artifacts?" An answer is provided using a scale space viewpoint, where one considers the entire family of smooths indexed by the bandwidth. Different bandwidths represent different "levels of resolution of the data". Significance of features that are characterized by Zero crossings of the derivative (such as bumps) is easily understood, assessed and presented, simultaneously over all resolutions, via a color map in scale space.

2. ***FUNFITS: Fitting Functions to Data***
Nychka, Douglas, National Center for Atmospheric Research and North Carolina State University

Abstract: FUNFITS is a suite of functions that enhance the S-PLUS statistical package and facilitate curve and surface fitting. This software grew up as a project to augment S-PLUS with additional nonparametric fitting strategies. Part of this effort was to focus on three areas rich in applications of function estimation and inference: spatial statistics, response surface methodology and nonlinear time series/dynamical systems. This activity has also lead to methods for space filling designs, appropriate when the response is expected to be a complex surface. One unique feature

of FUNFITS is the integration of thin plate spline methodology with the more general estimators based on spatial processes. This functionality is implemented completely in the S language and so the algorithms and source code are easily accessible. The core methods implemented in FUNFITS are object driven, including prediction, plot and summary functions that help the user interpret results and visualize the estimate.

3. Some Applications of Spline Smoothing

Gu, Chong, National Institute of Statistical Sciences

Abstract: *We will be presenting applications of the spline smoothing techniques in some ongoing NISS projects. Detailed summaries will be available soon as we make further progress.*

1.4 asa.competit.04

Sponsoring Section/Society: Government Statistics Section ASA

Session Title: The Implications of the North American Industrial Classification System (NAICS) for Official Statistics

For most of this decade, the United States, Canada, and Mexico have worked tointegrate their industrial classification systems, while updating the systems to reflect technological changes and innovations. The North American Industrial Classification System (NAICS) is in place now and government statisticians face a new challenge converting statistical programs to the new system while preserving time series and educating users about NAICS changes. The impact of the changes in converting to NAICS will be enormous, both for the government statisticians making these changes and for the users of the official statistics they produce. The conversion process will take many years to complete and will have unexpected side effects such as redefinition of standard occupation codes. The three speakers in this session were appointed to be their country's official representative for the development of the integrated classifications and for the coordination effort to implement the revised codes.

Session Organizer: **Cox, Brenda G.** Mathematica Policy Research Inc.

Session Chair: **Cox, Brenda G.** Mathematica Policy Research, Inc.

1. ***NAICS and U.S. Statistics***
   Ambler, Carole, U.S. Bureau of the Census

Abstract: The North American Industry Classification System (NAICS) was developed in cooperation with Statistics Canada and Mexico's Instituto Nacional de Estadistica, Geografia e Informatica (INEGI) to provide for comparable industrial statistics across the three countries. NAICS is the first ever classification system to be constructed on a consistent conceptual framework. Such a framework will provide consistent statistics across the three countries that can be used for measuring productivity and *unit labor costs, constructing input-output tables, and other uses that imply the analysis of production relationships in the economy. This paper discusses the impact that NAICS will have on U.S. industrial statistics and focuses on Bureau of the Census and Bureau of Labor Statistics Programs. Issues such as the redesign of the current services annual program at the Census Bureau and the need to produce time series data are also discussed.*

2. NAICS: The Canadian Perspective

Nijhowe, Shaila, Statistics Canada

Abstract: The North American Industry Classification System (NAICS) has been developed against the background of the North American Free Trade Agreement (NAFTA) and the need for comparable industry statistics to analyze issues of industrial performance and productivity for which a supply side approach was adopted in its creation. This paper will discuss the impact of the development of NAICS on the annual business statistics program of Statistics Canada in terms of the representation of the structure of the Canadian economy. Issues relating to the conversion of the Business Register, the phased conversion of the annual surveys and the need to produce NAICS based statistical time series will also be discussed.

3. NAICS and Official Statistics in Mexico

Ordaz, Enrique, INEGI, Mexico

Abstract: Jointly developed in cooperation with the statistical agencies of the United States and Canada, the North American Industrial Classification System (NAICS) will provide users with comparable data and a new description of the three countries' economic structure. This paper discusses the issues associated with this integration, as well as the process of NAICS implementation in INEGI's programs of economic census and surveys and in particular treatment of time series.

Discussant: **Werking, George** U.S. Bureau of Labor Statistics

Carole Ambler, Shaila Nijhowe, Enrique Ordaz

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Sponsoring Section/Society: Sections Government Statistics

Session Title: Improving Survey Quality: Can We Develop Better Measures of Quality, and Will They Help?

Statistical organizations strive continuously to improve the quality of their surveys. Quality, however, can be hard to measure. Some of the dimensions of quality most important to customers and data users are often the most elusive to quantify. Changing survey practices may also produce new dimensions of quality that require new measures. What measures do statistical organizations use to assess how successful they are in improving quality? Are better measures needed to provide the feedback organizations require to monitor performance? Do policy makers, sponsors, and data users find the measures useful?

The Australian Bureau of Statistics, Statistics Canada, and the U.S. Census Bureau are reviewing or developing more formal quality assurance frameworks, or have developed programs requiring innovative quality measures. The speakers will discuss their experiences in defining dimensions of survey quality; developing consistent, timely, and new measures; and using the measures to monitor and improve their surveys.

Session Organizer: **Atrostic, B.K.** U. S. Bureau of the Census
Session Chair: **Bowie, Chester** U.S. Bureau of the Census

1. TBA
Linacre, Susan, Australian Bureau of Statistics

Abstract:

2. TBA
Smith, Philip, Statistics Canada

Abstract:

3. TBA

Atrostic, B.K., U. S. Bureau of the Census

Abstract:

Discussant: **Martin David** University of Wisconsin – Madison

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Sponsoring Section/Society: Biopharm

Session Title: Permutation Tests in Clinical Trials

Permutation or exact tests are often considered for use in the evaluation of clinical trials and epidemiologic studies. In this session, examples are used to illustrate the utitility, strength, and limitations of permutation tests. Presentations will describe the dependence of such tests on the observed test statistics and methods for ameliorating this dependence , the utility or rank-based alternatives for analysis of ordinal outcomes, the advantages of mutiple outcome permutation tests in identifying important individual outcomes, and the development of exact tests for detecting familial disease clusters and risk factors.

Session Organizer: **Vance Berger** Food and Drug Administration

1. Issues on Randomization Tests: Applications in Analysis of Ischemic Stoke Lesion Volume in the NINDS t-PA Strok Trial

Lu, Mei, Henry Ford Health System
Barbara Tilley, Henry Ford Health System
Shuhui Li, Henry Ford Health System

Abstract: The NINDS Stroke Trial demonstrated the effectiveness of tissue-type plasminogen activators (t-PA) given within three hours of stroke onset for the treatment of acute ischemic stroke. This effectiveness was defined as clinical recovery measured at three months. Assessment of the impact on stroke lesion volumes measured at three months is desirable. We initially proposed an analysis for the effect of t-PA on stroke lesion volume using randomization tests, given the highly skewed data and the distribution-free assumption for randomization tests. However, we encountered difficulties in analyzing th estroke lesion volume. Results from randomization tests are dependent on test statistics calculated from observed data. In this paper, we discuss the aspects of randomization tests and their limitations, illustrate our *findings in analyzing the stroke lesion volumes for the effect of t-PA, and compare randomization tests with nonparametric statistics. To study the effect of t-PA on the stroke lesion volumes, we finally proposed a parametric analysis using a generalized estimate equations (GEE) approach on the transformed data and validated the results using randomization tests with a relevant test statistic. This experience with the NINDS t-PA trial data emphasizes that randomization tests are useful for clinical trials but have limitations. The choice of test statistics influences randomization tests, and the choice of test statistics should be appropriate to the given data and hypotheses. Randomization tests are equivalent if test statistics are equivalent.*

Key Words: Randomization Test; Permutation Test; Exact Test; Nonparametric Test; GEE; Robustness; Statistical Validation.

2. A New Look at Rank Tests in Ordered 2 x k Contingency Tables

Permutt, Thomas, Food and Drug Administration
Vance Berger , Food and Drug Administration

Abstract: The P-P plot allows properties of rank tests in trials with two groups and ordinal outcomes to be visualized. We consider several tests that have been proposed in this application (Smirnov, Wilcoxon, and maximum chi-square). We compare them to the van der Waerden test, well known but not in this setting, and a new, cumulative chi test. We conclude that rank tests are a viable alternative to a priori assignment of parametric scores for outcomes. Both Smirnov-like tests and Wilcoxon-like tests may be useful. However, both the Smirnov and Wilcoxon tests are bad examples of their types in that they give equal weight to some deviations that are highly improbable under the null hypothesis and to others that are much less improbable. The maximum chi-square test is more powerful than the Smirnov test, and the van der Waerden and cumulative chi tests are more powerful than the Wilcoxon test, over a wide region of the parameter space.

3. A Comparison of One-Sided Methods to Identify Significant Individual Outcomes in a Multiple Outcome Setting

Troendle, James, National Institute of Child Health and Development
Legler, Julie L., National Cancer Intstitute

Abstract: We compare two approaches to the identification of individual significant outcomes when a comarison of two groups involves multiple outcome variables. The approaches are all designed to control the familywise error rate in the strong sense. The first approach is initially to use a global test of the overall hypothesis that the groups are equivalent for all variables, followed by an application of the closed testing algorithm. The global tests considered here are ordinary and generalized least squares, an appoximation to the likelihood ratio test, and an approximation to the most powerful similar test for a simple normal alternative. The second approach is that of stepwise testing, which tests the univariate hypotheses in a specific order with appropriate adjustment to the univariate p-values for multiplicity. The stepwise tests considered are those of Holm and Hochberg, along with step-down and step-up permutation tests. The permutations allow the tests to incorporate the correlation between outcomes without any restrictive assumptions.

We illustrate the tests with two examples of birth outcomes: a comparison of cocaine exposed newborns to control newborns on neurobehavioral and physical growth variables, and, in a separate study, a comparison of babies born to diabeticmothers and babies born to non-diabetic mothers on minor malformations. Simulations are used to provide a basis for chosing among the procedures considered.

4. Exact Statistical Inference in Familial Disease Clusters

Zelterman, Dan, Yale University
Yu, Chang, Yale University
Claus, Elizabeth B., Yale University

Abstract: *In many epidemiologic studies the first indication of an environmental or genetic contribution to the disease is the way in which the diseased cases cluster within the same family units. We assume that all individuals are exchangeable, except for their disease status. This assumption of exchangeability is used to test the initial hypothesis of no familial link with the disease. Conditional on the distribution of the sizes of the various familial units, we obtain the exact probability of observing a given set of disease cluster frequencies. The expected frequencies and other moments are given. Three numerical examples demonstrate these methods. We describe an algorithm for obtaining exact statistical inference by enumerating all possible outcomes consistent with the numbers and sizes of the family units. A parametric model is given to identify useful risk factors for the disease outcome.*

Keywords: exact inference; genetics; statistical computing; multivariate discrete distributions.

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Sponsoring Section/Society: Biopharm

Session Title: Methodological Issues in the Analysis of Drug Product Stability Data

Session Theme: There are a number of issues in the analysis of stability data that are of concern to pharmaceutical companies and the Food and Drug Administration (FDA). Among these issues are 1) whether the data from different batches can be pooled to estimate a common slope and/or error variance, 2) whether different drug products, that is, the same drug in a different package and/or strength, can be considered in the same analysis, and 3) whether drug product batch should be considered a fixed or random effect. Stability data analysis issues will be the theme of this session.

Session Organizer: **Pack, David J.** Hoechst Marrion Roussel

1. One Stability Analysis–Multiple Drug Products
Pack, David J., Hoechst Marion Roussel

Abstract: There is considerable uncertainty in the pharmaceutical industry about the extent to which stability data from different packages and/or strengths of the same fundamental form of one drug can be or should be analyzed in the same stability analysis. This presentation will examine this issue, considering the 1987 FDA stability guideline, the FDA software for stability analysis, publications on stability analysis by FDA authors, Hoechst Marion Roussel FDA review experiences, the 1993 ICH stability guideline, and the 1998 FDA stability guidance.

2. Analyzing Packages and Strengths Together or Separately in Bracketed and/or Matrixed Stability Studies
Nordbrock, Earl, Anesta Corporations

Abstract: *The method of analysis which will be used for a bracketed and/or matrixed stability study must be decided before the design can be evaluated if the evaluation involves the calculation of the design's power. This presentation will contrast some of the fixed effect models which have been proposed for the analysis of matrixed and/or bracketed stability studies, focusing on when packages and/or strengths should be combined in a single analysis. Example questions are 1) Should physician-sample and market-size bottles be combined in a single analysis, 2) Should bottles and blisters be combined in a single analysis, and 3) Should multiple strengths be combined in a single analysis?*

3. Drug Product Batch-Fixed or Random Effect in Stability Analysis Models

Shao, Jun, University of Wisconsin

Abstract: *Shao and Chow's 1994 Biometrics paper presented a methodology for determining labeled shelf-life in a stability analysis with a small number of batches treating batch as a random effect. This presentation will first briefly summarize the random effect methodology, with any enhancements made since 1994. The presentation will then discuss practical aspects of pharmaceutical industry use of a random batch effect stability analysis, including the number-of-batches from which data would be required to support the analysis and the extent to which industry companies would be capable of applying the random effect methodology.*

Discussant: **Tsong, Yi** FDA-CDER

1.8 asa.competit.08

Sponsoring Section/Society: ASA Biometrics

Session Title: Spatio-Temporal Modelling of Small Area Health Data

This session focusses on the a developing area within epidemiology which has considerable import for informing policy in health resource allocation and assessment of environmental health risk. The analysis of spatio-temporal patterns of disease incidence has considerable importance in areas of health surveillance(early detection of adverse incidence) and in understanding of epidemiological processes. This session featuresa number of diverse approaches to this field which is fast evolving, and a spectrum of aopplication areas is also represented,from disease cluster detection to the analysis of hidden structure via mixtures.

Session Organizer: **Lawson, Andrew** University of Abertay Dundee
Session Chair: **TBN**

1. ***Space-Time Mixture Modelling in Health Data***
   Boehning, Dankmar, Free University, Berlin
   Schlattmann, Peter,

Abstract: Mixture models for the construction of disease maps have been suggested in parametric(Clayton and Kaldor, Biometrics 1987, 671-687) and nonparametric form (Schlattmann and Boehning, Statistics in Medicine 1993,1943-1950). The discrete nature of the nonparametric mixture model estimator has been exploited to bind each component with a colour (or grey pattern) in the map which leads to a natural way of disease map construction with the program DISMAP=20(Schlattmann, 1996, Statistics in Medicine, 931). However, in these models time effects are not allowed. Here we consider ways to incorporate replications of area counts of disease cases in the mixture model which then would enable the disesase-mapper to model space-time clustered data simultaneously.

2. On Space-Time Cluster Modelling via MCMC Methods

Lawson, Andrew, University of Abertay Dundee, UK
Clark, Allan,

Abstract: The analysis of disease clustering is of considerable importance when time of occurence as well as spatial location are observed. This is especially true when surveillance systems are to be established. In this work we adopt a parametric modelling approach where clusters are regarded as objects to be estimated and where different types of clusters can be defined,depending on their space-time characteristics. The development of MCMC methods based on reversible jump sampling is extended to the case where temporal and spatial and spatio-temporal clusters are allowed.

3. On the Bias of the Knox Method and Other Space-Time Interaction Tests

Kulldorff, Martin, National Cancer Institute
Hjalmas, Ulf,

Abstract: The Knox method, as well as other tests for space-time interaction, are biased when there are geographical population shifts so that different regions have different percentage population growth. In this talk, the size of the population shift bias is investigated for the Knox test, and it is shown that it can be a considerable problem. A method for constructing unbiased space-time interaction tests is then presented and illustrated. Practical implications are discussed in terms of the interpretation of past results and the design of future studies.

4. Spatio-Temporal Modelling of Mortality Data for Multiple Causes of Death

Leyland, Alistair, University of Glasgow, UK
Langford, Ian,
Goldstein, Harvey,
Rashbash, J.,

Abstract: *This paper illustrates how it is possible to develop a spatial model for counts of diseases occurring in discrete geographical areas as a multilevel model with heterogeneity effects and spatial effects considered to be random and correlated across areas. Such an approach has the advantage that it permits the extension of the model to include other levels of nesting. The model can therefore be extended to include temporal effects either by considering the time points to be repeated measures within areas or by modelling random variation as a function of temporal distance across areas in the same way that physical distance is modelled for the spatial effects. Similarly, a further extension means that multiple responses can be modelled for each area within each time point. This approach is illustrated on cause-specific mortality data for small geographical area population approximately 1000) within Scotland.*

Discussant: **TBN**

1.9 asa.competit.09

Sponsoring Section/Society: ASA Biometrics Section

Session Title: The Impact of Patient Compliance

The need to assess patient compliance in clinical trials involving medication is widely recognized. The failure of patients to adhere adequately to prescribed medication is an important medical problem. Studies have demonstrated the prevalence of poor adherence across all types of regimens and diseases. Treatment efficacy cannot adequately be evaluated without valid measures of patient adherence. The use of careful and sensitive instruments to measure adherence behavior in a clinical trial is important in developing new therapies.

Unless appropriate account is taken of compliance problems in clinical trials, policies based on these trial findings may be misguided. Moreover, overlooking compliance problems in the general population may yield health care policy recommendations that are impractical or ineffective in actual application.

Session Organizer: **Ting, Lee Mei-Ling** Harvard Medcal School
Session Chair: **TBN**

1. Sensitivity Analysis and Non Complance in Randomized Trials

Robins, James, Harvard School of Public Health

Abstract: In randomized trials with noncompliance, it is often of interest to try to estimate the effect of treatment had there been complete compliance. However the effect under full compliance is not identified without strong untestable aasumptions. As a consequence, three approaches are available. First, compute bounds for the effect under full compliance. Second quantify uncertainty in a prior distribution and do a Bayesian analysis. Third conduct a sensitivity analysis. This talk offers a new approach to sensitvity analysis and shows how it can recover both results obtained under the bound approach and the Bayesian approach, while offering *greater flexibility and insight. Our appoach derives from a theorem stating that although the odds of becoming noncompliant at each time t conditional on the possibly unobserved "outcome under complete compliance" is not idenified, nonetheless given this "selection bias" odds as a function of t, the distribution of the "outcome under complete compliance" is nonparametrically just identified.Hence in a sensitivity analysis, we vary these "selection bias" odds.*

2. Estimating the Effect of Observed Exposure in Experimental Settings

Goethebeur, Els, University of Ghent, Belgium

Abstract: *In their 1991 paper, Efron and Feldman model the relationship between potential placebo response, and the effect of a possible drug exposure. They allow explicitly for an interaction between placebo response and drug dose effect. In doing so they provide measures of effectiveness in complier subgroups (like the effect of full compliance for the subgroup of patients who were full compliers with their assigned treatment), and efficacy at different potential exposures (like the effect of full compliance exposure over the entire study population). These parameters are estimated under the assumption of some form of exchangeability between compliance with placebo and compliance with treatment. In a simulation, Albert and Demets (1994) demonstrate how strong the biases can be in such model, when the assumption of comparable patients in similar compliance subgroups on treatment and placebo are not fulfilled.*

In this talk we show that the structural mean model (Robins, 1994, Goetghebeur and Lapp, 1997) can be used to estimate all the parameters of interest in the model of Albert and Demets, provided a baseline covariate can be identified which is associated with placebo response or treatment compliance, but which does not interact with the added treatment effect. These estimators are consistent even for selective noncompliance and noncomparable compliance groups between treatment and placebo. In return, they rely on the parametric description of the 'causal' or structural

relationships. Ocne this is correctly specified, the SMM model also allows to find the average relationship between treatment compliance and placebo response. We will move on to discuss sensitivity to this new level of structural assumptions.

3. The Impact of Patient Compliance on Steady State Pharmacokinetics

Chow, Shein-Chung, Biostatistics and Data Management, Covance
Wang, Wenping, Janssen Research Foundation
Hsuan, Francis, Temple University

Abstract: Physicians commonly prescribe drug products in a multiple dosage regimen for prolonged therapeutic activity. To study the effect of multiple dosing on drug concentration in blood, researchers often employ a deterministic model with the assumptions that drugs are administered at a fixed dosage, with fixed (usually constant) dosing intervals. In practice, as it is well known in the medical community, patients may not follow such a rigid schedule. Hence, two possible scenarios might occur: patients might not take the prescribed dosage, resulting in variable dosing size; or they might not adhere to the dosing schedule, resulting in irregular dosing times. This paper intends to lay out a probability framework to model these two types of non-compliance and consequently study their impact on the steady state pharmacokinetics.

When studying multiple dose pharmacokinetics, the principle of superposition is the key tool. In this paper, the principle of superposition in the presence of non-compliance is formulated generally as a recursive formula. With this formula, we are able to generalize the notion of steady state in multiple dose pharmacokinetics given non-compliance. Using the compliance models and the principle of superposition, important pharmacokinetic parameters are rigorously studied. Factors affecting the steady state trough concentration are characterized through a simulation study. The relationship between the compliance index and the average concentration at steady state is established. This result generalize the classic result about the equality between the single dose area *under the curve (AUC) and the multiple dose AUC. Using theophylline (an antiasthma agent) as an example, we demonstrate that non-compliance causes the drug concentration time curve to exhibit an increased fluctuation. The increase in fluctuation due to non-compliance cannot be explained with the use of the classical deterministic multiple dose model. A practical question – the number of doses needed to reach steady state, is answered both asymptotically and in a small sample study.*

4. Modelling Compliance Using Electronic Monitors

Lee, Mei-Ling T., Harvard Medical School
Choo, Peter, Harvard Medical School

Abstract: Harvard Pilgrim Health Care is the largest health maintenance organization in New England with one million members at its inception in 1994. Three hundred and thirty individuals consented to participate in the study. The Medication Management System(MEMS) was utilized to electronically monitor patient compliance during the investigation of assessment of adherence to antihypertensive therapy. Adherence was determined from patient interview, pill counts, review of pharmacy dispensing records, and electronic monitoring over an approximately three month period. Different means of representing adherence data from electronic monitors are examined. The various methods of adherence assessment are compared with each other.

1.10 asa.competit.10

Sponsoring Section/Society: ASA Health Policy Statistics

Session Title: Statistical Tools for Studying Health Care Costs: What Works and Where Do We Need Improvements?

Hillary Clinton, CEO's, drug companies, government officials and patients share concerns over health care costs. This session focuses on several aspects of the problem. Breast cancer screening has been shown to reduce mortality rates in some age groups of women. The first talk considers the cost-effectivenss of targeting certain risk groups for this screening. This talk is followed by one which discusses pitfalls one often encounters when using quality of life years and discounting of later life years in a cost-effective analysis. Examples will be discussed in which the study results (and conclusions) were highly dependent upon the particular weighting method used. The third talk investigates statistical modeling of health care costs. The discussion is applied to the problem of casemix adjustment when setting payments to health plans for their patients. The talks are discussed by Sue Rosenkranz from Harvard Pilgrim Health Care, a large health maintenance organization in the Northeast.

Session Organizer: **Christiansen, Cindy L.** Harvard Medical School and Harvard Pilgrim Health Care
Session Chair: **Hilbe, Joe**

1. Breast Cancer Risk and Cost-Effectiveness of Screening Mammography

McGuigan, KA, UCLA School of Public Health, Dept Health Services

Abstract: The cost-effectiveness of a screening program can be facilitated by targeting high-risk populations, as the performance characteristics (positive predictive value) of a screener improve as a function of increased prevalence of disease in a population. Using data from the Breast Cancer Detection Demonstration Project (BCDDP), parametric (logistic regression) and *nonparametric (recursive partitioning, artificial neural networks) models are compared to determine which methods better discriminate cancer cases from controls based on known risk factors. Performance characteristics include model sensitivity, specificity, positive predictive value, and area under the receiver operating characteristic curve (ROC). The best-performing model is used to distinguish low vs normal and high risk groups for alternative screening schedules. Discussion addresses whether current information about epidemiologic risk factors can be used to obtain improved yields with lower overall costs, subject to the constraint of minimizing missed cases (false negatives).*

2. ***Dangers of Discounting and QALYs***
Palmer, J. Lynn, M.D. Anderson Cancer Center

Abstract: Many traditional methods of analysis of health care policy data use weighting methods which may make interpretation of their results difficult. Any analysis using quality of life years as an outcome variable should make explicit in its conclusions how weighting or discounting of early versus late life years was determined, and how its conclusions would have changed if slight adjustments in these weights would have been made. This presentation will include examples of how these difficulties can be (easily) encountered and how results can be clearly presented.

3. ***How Well Do Models Work? Predicting Health Care Costs***
Ash, Arlene S., Boston University School of Medicine

Abstract: The goal is to pay health plans (such as HMOs) for the expected cost of care for the persons they enroll. Models based on age and sex can reliably distinguish population subgroups whose costs differ by as much as 10 to 1; however, R-squares for age-sex models rarely exceed 0.02. Health-based predictions, such as those produced by Diagnostic Cost Group (DCG) models, explain more of the variation, can detect subgroups whose costs differ by more than 100 to 1 and have larger R-square values, but still, generally

less than 0.10. In the context of producing models to be used in setting payments to health plans for their enrollees, we address questions such as: how much better is one model than another? in what way does a model fail? how good is good enough?

Discussant: **Rosenkranz, Susan L.** Harvard Pilgrim Health Care

1.11 asa.competit.11

Submitted by ASA-ENVR for competition

Panel Session Title: How Low Can We Measure: The Statistics of Detection and Quantitation

Session Organizer: **Coleman, David** Alcoa

Abstract: A multitude of statistical issues surrounds the seemingly simple question: "How low a concentration or level can we reliably measure or detect?" This question is pertinent to environmental sciences and analytical chemistry, but also to medical sciences and national defense. In this session, four distinguished panelists with diverse background present and tackle some of these issues, then discuss and debate the merits of various solutions. One concern is how to balance detection sensitivity with false positives/false alarms. Also important is selecting a population subsample; estimating between-lab and within-lab sources of bias and variation; developing calibration methods that will work in the face of heteroscedasticity and the presence of outliers; describing the relation between measurement uncertainty and significant digits; and applying equivalence testing.

The first panelist will comment on the statistical and conceptual properties of various estimators for the quantification limit and address issues of bias, variability and robustness. The second panelist will describe the calculation of detection limits for ion-chromatographic data and discuss the strength and weaknesses of two approaches. The third panelist will comment on the application of statistical models to accommodate heteroscedasticity and traditional laboratory approaches for estimating detection limits. The fourth panelist will describe the newly adopted ASTM standard practice for detection and the proposed standard practice for quantification.

This session addresses the theme of statistics as a guide for policy. Everyone has or should have an interest in how low a concentration - such as lead in water, PCB's in soil, carbon monoxide in air - can reliably be measured. The requirement to protect human health and ecosystems has caused regulatory agencies to push for lower limits on pollutants, but the ideal 0% is unattainable; so policy must be established to determine acceptably low limits. That policy should be based on statistics, analytical chemistry, and practical considerations.

This session will be of interest to applied statisticians. Because all measurements are uncertain, statistics and analytical chemistry must be used jointly to estimate the lowest concentration that can be reliably detected and the lowest concentration at which one can reliably report a numerical measurement value. Issues at hand that will be discussed and are of interest to applied statisticians are selection of sample population, biases (e.g., between labs), heteroscedasticity, blind trials, false detections, power of detection, significant digits, and calibration.

This session will be of interest to members of other ASA sections including the Sections on Physical & Engineering Sciences, Government Statistics, Biometrics, and Health Policy. Statisticians, environmental scientists, and policy-makers in government regulatory agencies, USGS, DoD, and NIST will be interested in this topic.

Session Chair: **TBN**

Gibbons, Robert University of Illinois
Vanatta, Lynn Air Liquide
Davis, Charles Environmetrics & Statistics Limited
Coleman, David Alcoa

1.12 asa.competit.12

Submitted by ASA-ENVR for competition

Cosponsored by the International Association of Mathematical Geologists

Session Title: Advances in Geostatistics

Sponsored by: ASA Section on Statistics and the Environment (ASA-ENVR) and by the International Association of Mathematical Geologists (IAMG). The primary aim of the IAMG is to promote international co-operation in the application and use of mathematics in geological research and technology. In keeping with this aim, IAMG is interested in fostering increased collaboration with statistical organizations, hoping that this will result in increased cross-disciplinary research. Two of IAMG's journals, Mathematical Geology and Computers and Geosciences, regularly publish state-of the-art theory and methodology pertaining to environmental statistics, spatial statistics, and geostatistics. Many ASA/ASA-ENVR statisticians, particularly those whose research interests include spatial statistics, are members of IAMG or read its journals.

Session Content: The purpose of the session is to familiarize the JSM audience with the statistical work of internationally-renown researchers in other disciplines that routinely use and develop statistical methodology, most notably in geostatistics, in their research. The intent is to foster future collaboration/educational opportunities between interested JSM participants and IAMG scientists and to encourage ASA participation at international conferences sponsored by the IAMG or other, similar international organizations. Most of the speakers for this session do not usually attend the JSM, and many JSM members may not attend the international meetings that often serve as the primary forum for the introduction of new methods in spatial statistics and geostatistics. Since these speakers do not normally attend the JSM, necessary funding for these speakers will be provided by the IAMG.

Session Organizer: **Gotway Crawford, Carol A.**
Session Chair: **Gotway Crawford, Carol A.**

1. A Solution to the Lognormal Kriging Problem

Clark, Isobel, University of the Wittswatersrand

2. The Present State-of-the-Art of Geostatistical Simulation
Lantejoul, Christian, Centre de Geostatistique

3. Bayseian and Other Approaches to the Analysis of Geostatistical Data
Omre, Henning, University of Trondheim

Dr. Henning has been invited to speak about his research on Bayesian/Hierarchial Markov Chain Monte Carol analysis of geostatistical data.

Discussant: **Switzer, Paul** Stanford University

Dr. Switzer has been invited to be the discussant. Alternatives for the 2 invited but not yet committed participants include: Andre Journel from Stanford University; Mohan Srivastava, FSS Internations, Vancover, Canada; Peter Dowd, Univeristy of Leeds, England; and Pierre Goovaerts who is now affiliated with the University of Michigan and would speak about space-time modeling in agriculture.

1.13 asa.competit.13

Submitted by ASA-ENVR for competition

Session Title: Impediments to Good Statistical Practice in Environmental Decisions: Overcoming Regulatory Hurdles

This session provides in-depth discussions of difficulties and issues that arise when statistics are applied to environmental decision making and explores the interface between statisticians and regulators. Many applied statisticians deal with such settings. The organizer has brought together a group of speakers with much practical experience in applying statistics within regulatory frameworks. The first speaker will describe several case studies and discuss successes and failures in his attempts to apply statistics to decisions concerning the environment. The second speaker will discuss statistical issues in the debate on uncertainty and variability in risk assessments. The third speaker will describe some of the obstacles statistician face in communicating with regulators and put forth some guidelines for good statistical practices in environmental applications. The session should attract statistician from a wide variety of disciplines (biological, environmental, agricultural, ecological, and medical), those who work in consulting areas, and those who must communicate successfully with regulators.

Session Organizer: **Black, Kelly** Neptune and Company, Inc.
Session Chair: **Black, Kelly** Neptune and Company, Inc.

1. Facing Preconceptions and Fears about the Role of Statistics in Environmental Decision Making

Michael, Daniel, Neptune and Company, Inc.

Abstract: Good science, supported by valid statistics. While everyone might agree this should be the goal, it is often difficult if not impossible to implement in the environmental decision making arena. Federal and State regulations, in a effort to be less ambiguous, have in some cases become over prescriptive, and the regulatory reform process has fallen way behind the latest statistical wisdom. In addition, many regulators and project sci-

entists, have developed what statisticians would view as unsubstantiated fears and preconceptions concerning certain statistical sampling approaches, or the application of statistical tests. Therefore, to succeed in providing statistical support, statisticians have been forced to perform their work in a manner they deem either completely inappropriate or at least, suboptimal. This paper will use several case studies to clarify the nature of these problems, and present strategies which we have applied in our attempts to overcome these obstacles. Both successes and failures will be discussed, to assist in bringing these issues to the table and to open discussion amongst the statistical community.

2. Uncertainty and Variability in EPA Risk Assessments: The Need for a Statistical Perspective

Kelly, Elizabeth, Los Alamos National Laboratory

Abstract: Recent EPA risk guidance and policy and the influential report by the National Academy of Sciences titled Science and Judgment in Risk Assessment call for separating variability and uncertainty in human health and ecological risk assessments. However, a RISKANAL discourse (RISKANAL is a non moderated E-mail list) on this topic revealed confusion and disagreement among experienced risk assessors, not only about the requirement to separate variability and uncertainty, but also about the very definitions of these terms. This paper describes the confusion and contention in the uncertainty/variability debate, and identifies areas where the lack of a statistical perspective results in guidance that is weak or misleading. We also present some suggestions to improve the guidance and reduce confusion and contention.

3. Environmental Statistics and Regulators: Bridging the Communications Gap

Gilbert, Richard O., Pacific Northwest National Laboratory

Abstract: Statisticians talk statistical jargon; it is in our blood. Regulators often struggle with making decisions regarding the need for additional sampling or cleanup without adequate

knowledge of statistical concepts or methods. Statisticians like to use optimal tools, but those tools are often complex and difficult to understand intuitively. Furthermore, optimality is present only if certain assumptions about the underlying populations being sampled are indeed true. Some regulators may be fearful of such tools because they do not understand them. This presentation will discuss these and other realities facing the environmental statistician and consider how we as statisticians can do a better job of meeting the needs of regulators and other stakeholders. Folded into this discussion will be an attempt to define "Good Statistical Practice" in the environmental setting and to set out guidelines for its implementation. Some recently developed statistical methods will be used to illustrate concepts and provide examples to motivate discussions among statisticians.

1.14 asa.competit.14

Sponsoring Section/Society: ASA-SPES

Session Title: Current Trends In Multiresponse Surface Methodology

Purpose of the Session:

Multiresponse surface methodology is a relatively new area in response surface methodology (RSM). It concerns the design and analysis of experiments in which a number of response variables are of interest. One of the earliest applications of this new area is multiresponse optimization, which has attracted a lot of attention, especially among practitioners and research workers. There are, however, other interesting topics that have been developed in the multiresponse area. The purpose of this session is to provide exposure to such topics. In particular, testing lack of fit of nonlinear multiresponse models, and the use of generalized linear multiresponse models will be discussed in this session.

The proposed session should appeal to anyone interested in the general area of RSM. Engineers, statisticians in academia and the industry, and those involved in consulting involving multiresponse experiments should be interested. In past meetings, the multiresponse component of RSM has received little or no attention at all. One of the objectives of the session is to focus on the importance of the multiresponse approach in RSM. Furthermore, since this area is relatively new, it should appeal to those looking for new research problems in RSM.

Session Organizer: **Andre I. Khuri** University of Florida
Session Chair: **TBN**

1. Lack of Fit Tests for Nonreplicated Nonlinear Multiresponse Models

Neill, James W., Kansas State University
Forrest Miller, Kansas State University

2. Multiresponse Surface Methodology Under Generalized Linear Models

Valeroso, Elsie S., Montana State University

3. Past, Present, and Future Directions in Multiresponse Surface Methodology

Khuri, Andre I., University of Florida

1.15 asa.competit.15

Sponsoring Section/Society: Section on Statistical Education

Session Title: Working Environments for Newly Graduated Statisticians

The primary purpose of this session is to provide Ph.D. students in statistics with otherwise difficult to obtain information and insights into the job market and various working environments. Additionally, we hope to help these students better prepare for their job search and make more informed, intelligent decisions at this critical junction of their careers.

Session Organizer: **Cochran, James J.** Drexel University
Session Chair: **TBN**

1. ***Finding Your First Position***
   Cochran, James J., Drexel University

   Abstract: Various sources of information about jobs for graduate-degreed statisticians will be discussed. Assistance provided by JSM sponsors will be highlighted. Other professional organizations (e.g., INFORMS, DSI), Internet sites, and other sources, such as the Chronicle of Higher Education, will also be covered.

2. ***The Private Industry Environment***
   Keyes, Tim, General Electric Corporate Research and Development
   Ness, Angie, General Electric Corporate Research and Development
   Osborn, Brock, General Electric Corporate Research and Development

   Abstract: The qualifications that employers of statisticians in private industry are looking for will be discussed. The demands of various types of employers of statisticians in private industry (e.g., marketing research, engineering, financial analysis, industrial engineering, pharmaceuticals) will be addressed. The presentors will share their views on responsibilities of statisticians employed at small and large firms. Strategies for success in various private industry environments will be suggested.

3. The Government Environment

Griffith, Jeanne E., National Science Foundation

Abstract: *The qualifications that government employers of statisticians are looking for will be discussed. The statistical activities of the various federal agencies (e.g., Census Bureau, Department of Labor, Department of Defense, Centers for Disease Control, Food and Drug Administration, NSF) will be compared. Perspectives on differences in responsibilities of statisticians employed at the Federal, State, and Local levels will be presented. Strategies for success in the various government environments will be suggested.*

4. The Academic Environment

Hogg, Robert V., University of Iowa

Abstract: *The qualifications that academic employers of statisticians are looking for will be discussed. Similarities and differences between the mathematics, engineering, business, and medical academic environments (e.g., research funding, teaching loads, coverage of subject matter) will be addressed. Perspectives on differences in responsibilities of academicians employed at universities with varying levels of research orientation will be presented. Strategies for success in the various academic environments will be suggested.*

1.16 asa.competit.16

ASA Competition: Section on Epidemiology

Session Title: Estimating the Magnitude of Transmissible Spongiform Encephalopathy Epidemics in the United Kingdom: Bovine Spongiform Encephalopathy (BSE) and the Probable Link to the New Variant of Creutzfeldt-Jakob Disease (vCJD) in Humans

Estimation techniques for the magnitude of the BSE epidemic in Great Britain will be presented. The Age-at-onset approach estimates an upper bound to the epidemic with few parametric assumptions. The backcalculation approach simultaneously estimates necessary parameters and the size of the epidemic. The third presentation will address the problem of estimating the magnitude of the vCJD epidemic in humans given that the incubation distribution is long, variable and unknown.

Session Organizer: **MaWhinney, Samantha** University of Colorado Health Science Center

1. Estimating an Upper Bound on the BSE Epidemic in British Cattle

Samantha, MaWhinney, University of Colorado Health Science Center

Abstract: The Bovine Spongiform Encephalopathy (BSE) epidemic in British cattle has generated public health concerns and has significantly impacted the British agricultural industry. Backcalculation methods have been used to estimate infection incidence requiring distributional forms for incubation period and age at infection, allowing for maternal and horizontal transmission. Assuming all infections occur early in life, an upper bound is obtained for the number of infections without separately parametrising these distributions. This method relies on a generalised linear model estimated using an EM algorithm to account for the truncated data. As the epidemic matures, the average age at infection decreases and stabilises (a function of exposure and the feed ban *imposed in July 1988) and the upper bound approaches the actual number of infections. The primary analysis was restricted to the birth cohorts of cattle from 1984 to 1993. The bound for the total number of infections was estimated to be 1,061,400, which is consistent with earlier backcalculation results for all cohorts of 903,000 (840,000-1,250,000). The method is shown to yield robust estimates for the magnitude of the epidemic, assuming all infections occur early in life, without requiring the estimation of epidemiological parameters.*

2. Statistical Analysis of the British BSE Epidemic: Past, Present and Future

Donnelly, Christl, University of Oxford

Abstract: Backcalculation models describing the key processes determining the pattern of the Bovine Spongiform Encephalopathy (BSE) epidemic in British cattle are derived that allow for infection from feed as well as maternal and direct horizontal transmission. Heterogeneous susceptibility classes are also incorporated into the analysis. Maximum likelihood methods are used to estimate parameters and to obtain confidence intervals from available experimental and epidemiological data. A comprehensive sensitivity analysis of model parameters and distributional assumptions is presented. Additional validation is provided by fitting the model to independent data collected in Northern Ireland. Model estimates and predictions based on BSE case data for Great Britain and Northern Ireland, together with their implications, are reviewed, and future research priorities discussed.

3. Analysis of New Variant CJD Cases in Great Britain: What Can We Say Now? What Will We Be Able to Say Later?

Ferguson, Neil, Affiliation University of Oxford

Abstract: By September 30, 1997 22 cases of new variant Creutzfeldt-Jakob disease (vCJD) had been confirmed in Great

Britain. In March 1996, the Secretary of State for Health announced that 'There remains no scientific proof that BSE can be transmitted to man by beef, but the Committee have concluded that the most likely explanation at present is that these (10 vCJD) cases are linked to exposure to BSE before the introduction of the specified bovine offal ban in 1989.' Since this time, experimental studies have yielded strong scientific evidence linking BSE and vCJD. Backcalculation methods can be used to estimate future case numbers based on these initial cases; however, the lack of knowledge about the incubation period distribution results in high levels of uncertainty. The performance of backcalculation performed at various points throughout the time scale of the epidemic is evaluated under a variety of assumptions consistent with the currently available data.

Anderson RM, Donnelly CA, Ferguson NM, Woolhouse MEJ, Watt CJ, Udy HJ, MaWhinney S, Dunstan SP, Southwood TRE, Wilesmith JW, Ryan JBM, Hoinville LJ, Hillerton JE, Austin AR and Wells GAH. Transmission dynamics and epidemiology of BSE in British cattle. Nature 382, 779-788, 1996.

Donnelly CA, Ferguson NM, Ghani AC, Woolhouse MEJ, Watt CJ, and Anderson RM. The epidemiology of BSE in GB cattle herds: I. Epidemiological processes, demography of cattle and approaches to control by culling. Philosophical Transactions of the Royal Society London B 352, 781-801, 1997.

Ferguson NM, Donnelly CA, Woolhouse MEJ and Anderson RM. The epidemiology of BSE in GB cattle herds: II. Model construction and analysis of transmission dynamics. Philosophical Transactions of the Royal Society London B 352, 803-838, 1997.

Donnelly CA, Gore SM, Curnow RN and Wilesmith JW. The bovine spongiform encephalopathy maternal cohort study: its purpose and findings. Applied Statistics 46, 299-304, 1997.

Donnelly CA, Ghani AC, Ferguson NM, Wilesmith JW and Anderson RM. Analysis of the bovine spongiform encephalopathy maternal cohort study: evidence of direct maternal transmission. Applied Statistics 46, 321-344, 1997.

Ferguson NM, Donnelly CA, Woolhouse MEJ and Anderson RM. A genetic interpretation of heightened risk of BSE in offspring of affected dams. Proceedings of the Royal Society London B 264, 1445-1455, 1997.

Donnelly CA, Ghani AC, Ferguson NM and Anderson RM. Recent trends in the BSE epidemic. Nature 389, 903, 1997.

Donnelly CA, Ferguson NM, Ghani AC, Wilesmith JW and Anderson RM. Analysis of the dam-calf pairs of BSE cases: confirmation of maternal risk enhancement. Proceedings of the Royal Society London B to appear, 1997.

1.17 asa.competit.17

Sponsoring Section/Society: Health Policy Statistics Section

Session Title: Statistical Models and Methods for Health Care Policy Research

Session Organizer: **Christiansen, Cindy L.** Harvard Medical School and Harvard Pilgrim Health Care
Session Chair: **Bailey, R. Clifton** HCFA

1. Estimating the Effect on Survival of Detecting Cancers By Screening Using Instrumental Variables: An Example With Breast Cancer Screening

McIntosh, Martin, University of Washington, Department of Biostatistics and Fred Hutchinsen Cancer Research Center

Abstract: Evaluating the effectiveness of cancer screening trials has many technical difficulties. It is common to evaluate a trial by computing a p-value and estimating effect sizes with comparison groups constructed from the subjects treatment assignments, but using only those subjects who developed cancer (the "cancer cohort"); see for example Shapiro (Cancer, 1997), Shapiro, et. al (JNCI 1982), Chu, et. al (JNCI, 1988) for examples with breast cancer screening). The difficulty of evaluating these data are that (1) the screened group may find cancers earlier than in the unscreened population ("lead time" bias), (2) the screening may find cancers that go undiagnosed in the unscreened population, and (3) some subjects assigned to be screened may have refused.

Each difficulty makes constructing comparison groups difficult: to whom do you compare the screening group cancers? One solution to (1) is to follow subjects until well after the screening has stopped, then use all cancer cases in both groups for comparison. The solution to (2) has been to 'hope' that the long followup time finds the number of cancers in the unscreened group 'caught up' to those in the control group. If catchup does not occurr, then

the subjects cancer status depends on the treatment assignment (i.e., it is in the causal pathway), and treating it as a covariate does not lead to valid causal interpretation). Even if catchup does occur, including cancer cases who could not have been detected by screening attenuates the effect size estimate, and leads to substantial bias. Problem (3) has a similar difficulty, because a refuser who was assigned to the control would appear there as a complier, and so compliance staus too is effected by the treatment assignment, and cannot be treated as a covariate.

The methods to deal each of these have been ad-hoc, and admit substantial bias. Here we show how using the Imbens and Rubin (1996a, 1996b) causal framework for dealing with noncompliance can be adapted to analyze cancer screening trials, and gives a very simple and elegant estimate of the causal effect of screening (or screen detection) on patient outcomes (survival time, cancer stage, tumor size, lead time effect). This method deals with all these biases simultaneously.

2. ***Models for Health Care Planning***

Carrier, K.C., University of Alberta

Abstract: In health services research, as in any other social science research, the first step in data analysis is to identify the factors deemed relevant for inclusion in the estimation. The next pertinent decisions are the selection of the unit of analysis and an appropriate treatment of the parameters in the equation. In health services research, where health effects are potntially attributable to area level, or ecological variables, there are many critical methodological issues to ponder. All analytic approaches have some risks and some disadvantages. If the analytic results and recommendations were to be implemented successfully in practices of health care planning, it is imperative to understand these risks and disadvantages as well as advantages. Across Canada, health care reform has taken place recently. Using administrative and census data from three Canadian prairie provinces (Manitoba, Alberta, Nova Scotia), we explore weaknesses and strengths of some alternative approaches, with research objectives to efficiently and

objectively evaluate the health care reform. We will focus on the relationship between policy changes and changes in overall utilization of hospitals and physicians according to area of residence, area of service (urban and rural) and types of hospital (teaching, urban community, rural) by groups at risk (elderly and those in low socioeconomic conditions).

3. Using Difference (rather than ratio) Measures in Clustered Healthcare Data

Localio, Russell, University of Pennsylvania, Center for Clinical Epidemiology and Biostatistics

Ten Have, Thomas, University of Pennsylvania, Center for Clinical Epidemiology and Biostatistics

Abstract: Much theoretical and applied research on clustered categorical data relies on ratio measures (such as odds ratios) to demonstrate treatment or program effectiveness. These measures, while convenient to the statistician for theoretical reasons, are often less meaningful to the clinical or health policy audience. We investigate the methodological and practical challenges of using measures such as risk difference in the context of clustered health care data. Our example is a two-period cross sectional analysis of the process of cardiovascular care in 197 hospitals (and 23,000 patients) in one state in a program sponsored by the Health Care Financing Administration and its local PRO (Keystone Peer Review, Inc). With multiple endpoints per patient and differing numbers of endpoints per hospital, we also investigate the effects of the number of clusters (hospitals), the number of patients per hospital (cluster size), and the correlation of endpoints within hospital on the choice of estimation techniques. In addition, process endpoints being highly correlated within hospital, we shall address the impact of levels of within-cluster correlation on the choice of estimates.

Discussant: **Gatsonis, Constantine** Brown University

1.18 asa.competit.18

Sponsoring Section/Society: ASA Health Policy Statistics

Session Title: Assessment of Drug Interdiction Activities

Session Organizer: **Fries, Arthur** Institute for Defense Analyses
Session Chair: **Petrie, Carol (tentative)** National Research Council

1. NRC Study–Information and Research for Drug Abuse Policy

Petrie, Carol, National Research Council

Abstract: The National Research Council has begun a 30-month study entitled "Information and Research for Drug Abuse Policy", sponsored by the Office of National Drug Control Policy. The study is expected to lead to new insights on the strengths and limitations of current knowledge on drug control, and to identify information that can stimulate the development of both new data collection systems and advanced models that can respond to changing policy analysis needs in a cost effective and timely manner. This talk is focused on drug interdiction activities, and provides an update on study efforts to date.

2. Models Versus Data

Rivolo, Rex, Institute for Defense Analyses

Abstract: We provide a historical outline of research in the field of illegal drug use, treatment, and prevention, with a focus on recent published reports that have played major roles in the development of national and international drug interdiction policies. Reported results and conclusions from this body of research are shown to suffer from fundamental analysis flaws and to be inconsistent with empirical evidence. In particular, specifications of predetermined models appear to dominate over straightforward data presentations and summaries.

3. Variation in the Optimal Mix of Drug Control Interventions over the Course of a Drug Epidemic

Caulkins, Jonathan, Carnegie Mellon University
Feichtinger, Gustav, Vienna University of Technology
Tragler, Gernot, Vienna University of Technology
Behrens, Doris, Vienna University of Technology
Haunschmied, Josef, Vienna University of Technology

Abstract: There is considerable interest in what the optimal mix of drug control interventions is, but to date most work has not explicitly acknowledged the epidemic character of waves of drug use or the possibility that the optimal mix of interventions should change over time. This paper applies optimal control theory to some very simple models of drug epidemics to produce insights into this important policy problem.

Discussant: **TBN**

1.19 asa.competit.19

ASA Competition: Statistical Consulting Section

Session Title: The Use of Interactive Visual Software in Statistical Consulting

The purpose of this session is to examine the advantages and disadvantages of using statistical visualization packages, (e.g., JMP) in consulting practices. Increasing in popularity and use with the advent or faster workstations, these packages offer powerful tools to a consultant in terms of data analysis and displays and can engender dialogue between the consultant and the investigator in real time fashion. At the same time, their use raises questions in terms of the role of the statistician on a research project (are we still needed?) as well as questions concerning planned versus exploratory analyses.

In this session, we will provide an overview of the available packages and associated training programs, present case studies of their use in a variety of consulting settings, and hold a lively discussion of their potential for use/misuse in the field.

Session Organizer: **Kendall, Jenny** Private Consultant
Session Chair: **Davis, Sonia** Quintiles, Inc.

1. Training Statisticians in the Use of Visual Statistical Software Packages

Kendall, Jenny, Private Consultant
Schlotzhauer, Sandra, SAS

Abstract: We use JMP statistical visualization software as a common language tool for communicating among statisticians and non-statisticians. We teach engineers, scientists, clinicians, data managers, report writers, and analysts of all kinds how to use the software so they may investigate their data and design and analyze routine types of experiments.

Our experience has been that as a person becomes accustomed to the software, they learn to ask more and better questions of the

data. Rather than taking the place of the statistical consultant, the software helps the data analyst and the consultant to communicate more effectively with each other. By having the data analyst work with their data through the use of interactive statistical software, the statistical consultant can be freed from routine programming types of issues to deal with more interesting data analysis problems.

We have examples from several industries, including the semiconductor industry where our clientele base is engineers and technical managers, and the pharmaceutical industry, where our clientele may be clinicians, report writers, scientists, or statisticians.

2. Using Statistical Visualization in an Academic Consulting Environment

Best, Al M., Medical College of Virginia

Abstract: Aside from the numerical correctness of results, interactive statistical analysis software should be judged on how well it assists the data analyst in the entire process of: getting data into a proper form, inspecting the data, modifying and transforming the data, analyzing and visualizing the structure in the data (and the deviance from structure), interpreting the results, and transferring our understanding to paper in the form of a graph, figure, or text. In addition to strong data management, statistical, and graphic capabilities, software must be easy to use, provide methods for repetitive analyses, be well documented and supported, and allow for tuning and extending the software. It would also be preferable for software to assist in the design of studies, including power analyses. There is a wealth of software available, all of it wanting in one or more of these areas.

In an academic consulting environment, we get data from an endless variety of data base systems. We also work with researchers with, shall we say, a wide range of quantitative skills. The goal is to have them come in, load their data into our machine and step through the process of data analysis in real time. The perfect system would allow the researcher to be at the elbow of

the statistician while the process of analysis unfolds. Often there are impediments which make this far from seamless.

In any event, the well-equipped statistician can form a productive relationship with one's fellow scientist and with the data at hand. Both relationships unfold over time, with many fits and starts, triumphs and tragedies. I view statistics as one of the "helping professions." How do we be of most service to our colleagues? How do we teach our students this artful process? How can we turn these encounters into opportunities for our own professional development?

3. Incorporating Guidelines for Use in the Development of Interactive Statistical Software :

Young, Forrest W., University of North Carolina-Chapel Hill

Abstract:

Discussant: **TBN**

1.20 asa.competit.20

Sponsoring Section/Society: ASA-SOC

Session Title: Income Distribution and Inequality

The authors are well-known in the inequality field and their papers combine a topic of importance to the economy from a statistical viewpoint.

Developing robust measures of inequality is important in view of the increase in inequality during the 1980s and 1990s. The adage that 'rising

tides lift all boats' generally held true until the 1980s when, despite the second longest expansion since WWII, inequality continued to increase. While many papers have been written trying to decompose the reasons, there has yet to be a definitive answer. Thus developing and experimenting with new measures and approaches to estimating inequality is important. This session allows ASA to be part of the inequality dialogue and to hopefully take the lead in the associated measurement issues.

Session Organizer: **Shipp, Stephanie** Bur. of Census
Session Chair: **Formby, John** University of Alabama

1. An Exponential Family of Lorenz Curves

Slotjje, Daniel, Southern Methodist University
Sarabia, Jose-Maria, and Castillo, Enrique, University of Cantabria, Santander, Spain

Abstract: A new method for building parametric-functional families of Lorenz curves, generated from an initial Lorenz curve (which satisfies some regularity conditions) is presented. It is shown that these families can be ordered in a manner which leads to a hierarchy of Lorenz curves. The method starts from a generating Lorenz curve L0(p) and builds the family by increasing the number of parameters, which can be easily interpreted in terms of the elasticities of L0(p). The method is applied to the Exponential family, since they use the Exponential Lorenz curves as their generating curves. The family is shown to contain an important number of classical Lorenz curves used in the existing literature.

Several properties of these families are analyzed. These include the population function, inequality measures and Lorenz orderings. A general method for the estimation of these families is given and applied to the Exponential family. Finally, an application is presented for data from various countries. The results are very robust across data sources.

2. A General Method for Measuring, Decomposing and Testing for Marginal Changes in Income Distributions

Chow, K. Victor, West Virginia University
Formby, John, University of Alabama
Zheng, Buhong, University of Colorado-Denver

Abstract: A general method for measuring and decomposing marginal changes in income and earnings distributions by population subgroup is presented and applied to the 1990-91 recession. The large sample properties of the marginal decompositions are derived and statistical inference procedures are developed. To illustrate the methodology, the SIPP eight wave longitudinal file is used to decompose marginal changes in the U.S. income distribution by race and earnings distribution by class of worker. The results provide strong evidence of negative and significant marginal decompositions for African-American families and private sector blue collar workers. These subgroups lost significantly more or gained significantly less compared to other families and workers at virtually every point considered in the quantile income and earnings distributions; they also incurred overall declines in income and earnings. Marginal decompositions of entire distributions showing gains and losses for other population subgroups are also presented. The evidence provides new insight into the short-run income dynamics associated with transitory incomes during a recession.

3. Statistical Inference via Bootstraping: An Application to the Distributional Implications of Taxes and Transfers in the U.S.

Zandvakili, Sourushe, University of Cincinnati
Mills, Jeffrey A., University of Cincinnati

Abstract: This paper introduces a statistical methodology for assessing the impact of changes in taxes and transfers on the size distribution of income. The manner in which researchers and public policy makers go about evaluating tax changes and their implications is inadequate. First, the methodology employed for tax and transfer incidence analysis is inappropriate; tax and transfer incidence must be analyzed in a dynamic and longitudinal framework with micro data to secure essential information. Second, the validity of inferences drawn based on observed changes in inequality resulting from such analyses has not been questioned, there is a need for statistical inference to determine the degree of confidence that can be placed in these results. There has been a lack of statistical inference to determine whether observed changes in the income distribution attributed to tax policy are systematic or just due to random variation in the sample. We are able to construct confidence intervals for various measures of inequality, and to conduct hypothesis tests to determine whether observed changes in the distribution of income are statistically significant.

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