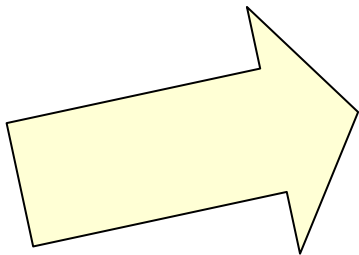


# ASAP Newsletter

The Philadelphia Chapter of the  
American Statistical Association



February, 2004



<http://www.amstatphilly.org/>

Check it out!

## PRESIDENT'S CORNER

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I'm pleased to report that we have three excellent speakers on a wide range topics for our **Spring Meeting on Thursday, March 11, 2004**. First, Prof. Joe Pigeon, Villanova University, will present a pharmaceutical example involving an assay to measure the potency of a vaccine to illustrate the use of simple data analysis techniques in some experimental design settings with a complex multiple error structure. Next, Dr. Gordon Lan, Fellow of ASA, Aventis Pharmaceuticals, will present a two-stage trial in which a winner is selected at the end of stage I from two candidates and only the winner and control will continue into stage II. Finally, Prof. Walter Hauck, Thomas Jefferson University, will describe a USP (United State Pharmacopeia) quality control test for releasing solid dosage batches: uniformity of content, and associated sample size and acceptance criteria questions. I sincerely hope that you will join us for this stimulating Spring Meeting. Please **RSVP by March 5**. Your active involvement is vital to the sustained success of our local ASA chapter.

ASAP is again sponsoring **Pennsylvania Statistics Poster Competition** and **Delaware Valley Science Fair**. The poster competition (<http://www.math.iup.edu/paposters/>) is open to all students in grades kindergarten through senior high school in Pennsylvania. The Delaware Valley Science Fair (<http://www.drexel.edu/dvsf/>) is one of the oldest and largest Fairs in the country. It is designed as a vehicle for stimulating interest in science and technology among students in middle and high schools in the tri-state area. If you're interested in participating as an ASAP judge, you can register online (see page 5) or contact an officer (see page 8).

The election for 2004-2005 ASAP officers is just around the corner, with the following four positions set to expire on June 30, 2004: President; Vice President; Secretary; and Treasure. Please consider serving ASAP in one of these positions. You may contact me or any current officers if you're interested. Look for details on the election process in an upcoming newsletter.

As always, if you would like to suggest names of speakers for future meetings, propose topics for short course, etc., please don't hesitate to contact either me or any chapter officer. Contact information is available on page 8 and on the ASAP website.

~ Charles Tan

## CALENDAR OF EVENTS

Friday, March 5:	<b>RSVP deadline</b> for ASAP Spring Meeting
<b>Thursday, March 11:</b>	<b>ASAP Spring Meeting</b>
Wednesday, April 7	Delaware Valley Science Fair judging day

### ASAP SPRING MEETING: THURSDAY, MARCH 11

<b>DATE:</b> Thursday, March 11, 2004, 11:30am-3:30pm <b>LOCATION:</b> Holiday Inn, 432 Pennsylvania Ave, Fort Washington, PA (1-800-339-0209)		
<b>LUNCH DETAILS:</b>  Buffet: Fresh Fruit Salad; Tossed Garden Salad; Sirloin Tips with Mushrooms; Baked Chicken with Herb Seasoning; Meatless Baked Ziti; Wild Rice; Vegetable Medley; Rolls and Butter; Assorted Cakes; Freshly Brewed Coffee, Decaf, Tea, Iced Tea	<b>PROGRAM</b>	
	<b>TIME</b>	
	11:30 - Noon Noon - 1:00 1:00 - 1:05 1:05 - 1:50  1:50 - 2:35  2:35 - 2:45 2:45 - 3:30	Meeting check-in and payment Lunch Introduction – <i>Charles Tan (ASAP President)</i> <b>Complex Experimental Design and Simple Data          Analysis: A Pharmaceutical Example</b> – <i>Joe Pigeon          (Villanova University)</i> <b>Select the winner in drug development</b> – <i>Gordon Lan          (Aventis Pharmaceuticals)</i> Break <b>Batch Acceptance From Single and Multi-Stage Designs          Using Two-Sided Normal Tolerance Intervals with          Specified Content</b> – <i>Walter W. Hauck (Thomas Jefferson          University)</i>
<b>COST:</b> \$30 including lunch; \$15 for full-time students, retirees, and those <u>not</u> electing lunch.		

**Directions:** From the PA Turnpike, take Exit 339 – Fort Washington. After the tollbooth, follow the left-hand lane under the overpass. (**DO NOT TAKE THE ROUTE 309 RAMP.**) The hotel is 1/8 mile on the left. From Route 309, take the Fort Washington exit. (**DO NOT TAKE THE EXIT FOR THE PA TURNPIKE.**) Exiting will put you onto Pennsylvania Avenue. Stay in the left-hand lane. The hotel is 1/8 mile on the left.

**Registration:** Please register by Friday, March 5<sup>th</sup> to Ms. Risa Cuebas at [cuebasr@wyeth.com](mailto:cuebasr@wyeth.com), **specifying company/institution, whether or not you will be eating lunch, and if you are a student. PLEASE REGISTER IN ADVANCE** so that we have an accurate count for both lunch and number of seats. Pay by cash or check at the meeting. You may also register by mail: send information to Ms. Risa Cuebas, Wyeth Research COL B-5, P.O. Box 42528, Philadelphia, PA 19101.

### ABSTRACTS AND BIOSKETCHES

<p><b>Complex Experimental Design and Simple Data Analysis:          A Pharmaceutical Example</b>  <i>Joseph G Pigeon, Ph.D.</i>          Villanova University</p>
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*Abstract*

Very often in industrial multi-factor experiments, some factors may have a different error measure associated with them than other factors. This generally arises because it may be more difficult, more costly or simply not feasible to completely randomize the order of the experimental runs. The result of this restricted randomization is that multiple error measures are introduced into the experiment and the resulting analysis needs to account for these multiple error measures. Experimental designs that combine fractional factorials may have a multiple error structure that is even more complicated than the usual split plot experiment. In agricultural settings, these designs are often called strip plot designs and in industrial settings they may be called multiway split unit designs. As a consequence of this complex design structure, suitable mathematical models for the proper analysis of the experimental data are often quite difficult to specify and apply. This talk uses a pharmaceutical example involving an assay to measure the potency of a vaccine to emphasize the need for experimenters to recognize these types of experiments and advocates the use of simple data analysis methods for analyzing these types of experiments.

*Biosketch*

Joe Pigeon is a Professor in the Department of Mathematical Sciences at Villanova University. In addition, he works as a consultant in applied statistics, most frequently in the pharmaceutical industry. He received a B.S. in comprehensive science and an M.S. in applied statistics from Villanova University and a Ph. D. in applied statistics from Temple University. Prior to joining Villanova in 1987, Joe worked over 15 years in various fields of applied statistics for General Electric Company, McNeil Consumer Products Company, Rohm and Haas Company and Merck & Company. He is a member of ASQ, the Royal Statistical Society and the American Statistical Association, where he has served as President, Vice-President and Council representative of the Philadelphia chapter. His research interests include industrial statistics, experimental design, and statistical modeling.

**Select the Winner in Drug Development**

*Gordon Lan, Ph.D.*

Aventis Pharmaceuticals

*Abstract*

We study a two-stage design where two potential treatments A and B are being considered for development. These two treatments are compared to a control treatment C in a randomized clinical trial. In stage I of the study, patients are recruited into these three treatment groups and their responses are compared and a winner W between A and B will be determined. In stage II, the loser in stage I is dropped from further study and additional patients will be allocated only to treatment groups W and C. At the end of the study, the responses of all W and C patients in stages I and II combined will be compared to determine whether W is better than C.

We examine the distribution of the test statistic for this process. For the purpose of hypothesis testing, we start with a very simple normal approximation procedure, and then followed by the exact and the almost exact approaches. In the small sample case, normal approximation is replaced by an approximate t-distribution.

*Biosketch*

Gordon Lan, Ph.D., is a Statistics Fellow at Aventis Pharmaceuticals, Bridgewater, NJ. He joined Aventis in July 2002 after seven years at Pfizer and an academic career, including the appointments of Professor of Statistics at the George Washington University and Mathematical Statistician at the National Heart, Lung and Blood Institute of the National Institutes of Health. Dr. Lan completed his B.S. and M.S. in mathematics at Taiwan University, and his M.A. and Ph.D. in mathematical statistics at Columbia University. He learned biostatistics as a post-doc at the Department of Biostatistics, University of North Carolina - Chapel Hill. His research related to clinical trial design and sequential trials is part of the contributions for which he was elected Fellow of the American Statistical Association.

**Batch Acceptance From Single and Multi-Stage Designs Using Two-Sided Normal  
Tolerance Intervals with Specified Content**

*Walter W. Hauck, Ph.D.*  
Thomas Jefferson University

*Abstract*

One quality control test in the pharmaceutical industry is a test for uniformity of content of a batch prior to release of the batch to market. For batch acceptance by this or other quantitative tests of batch quality, one approach uses two-sided tolerance intervals of specified content. If the tolerance interval falls entirely within an acceptance interval, the batch is accepted. This has the form of a statistical hypothesis test. Once we recognize this as a statistical test, we can approach this problem with standard questions, such as, What sample size is required to be able to accept the batch with a desired power? Standard designs have been of two stages, so what is needed are methods for tolerance intervals for one- and two-stage designs for batch acceptance with desired power and specified type I level.

*Biosketch*

Dr. Hauck is Professor and Head of the Biostatistics Section, Division of Clinical Pharmacology, Thomas Jefferson University, Philadelphia PA. He received his B.S. in Mathematics and Economics from Carnegie-Mellon University in 1969 and his M.S. and Ph.D. in Statistics from Harvard University in 1970 and 1975, respectively. Prior to Thomas Jefferson, he worked at the Harvard Medical School, Worcester Polytechnic Institute, Illinois Cancer Council, Northwestern University Cancer Center, and the University of California at San Francisco. He is the author or co-author of over 175 peer-reviewed papers and has served as statistical consultant to working groups within FDA's Office of Pharmaceutical Sciences, the USP, and pharmaceutical companies. Current research interests include statistical methods for assessing equivalence and clinical pharmacology statistics.

## **DELAWARE VALLEY SCIENCE FAIR**

ASAP is looking for judges. Approximately 1,000 6-12<sup>th</sup> graders from the Tri-State area will compete April 6<sup>th</sup> through the 8<sup>th</sup> at the Fort Washington Expo Center. Winners earn prizes and the right to enter their original science project at the International Science and Engineering Fair in May. ASAP is sponsoring three “Special Awards” to students for the best use of statistics. Judging will take all day on Wednesday, April 7 beginning at 8am. Continental breakfast and a box lunch will be provided. If you would like to help judge posters, please speak with an ASAP officer and (see page 8) register online at <http://www.drexel.edu/dvsf/judging.htm> -- be sure to mention you are a “Special Awards judge” with ASAP. Thanks!

### **PASTA: PHILADELPHIA AREA STATISTICS TEACHERS ASSOCIATION**

Please contact Ruth Carver ([rcarver@germantownacademy.org](mailto:rcarver@germantownacademy.org)), Sue Peters ([peterss@aol.com](mailto:peterss@aol.com)), or Janice Ricks ([ricksj2@yahoo.com](mailto:ricksj2@yahoo.com)) for a meeting schedule and questions.

### **LIST A JOB POSTING IN THIS NEWSLETTER**

The Philadelphia Chapter of the ASA has over 300 members in a variety of specialties covering academics, industry and government. We can include your ads (less than 100 words text) in our newsletters for a nominal fee (\$25). We issue newsletters in February, May, and September. You are encouraged to include in your ads a brief description of the opening, your contact information, and a link to your web site or document that provides more details. Please send the payment (payable to ASA Philadelphia Chapter) to our Treasurer. Please email your text ads to one of the chapter officers. Here is the link to the contact information of chapter officers:  
<http://www.amstatphilly.org/Officers/officers.html>

## TREASURER'S REPORT

<b>BALANCE FORWARDED (31-Aug-03)</b>	<b>\$2,041.35</b>
<b>INCOME:</b>	
ASA Chapter Dues	
Jun - Nov 2003	\$1,001.00
Jun 1998	\$151.00
Jul 1999	\$156.00
Subtotal dues	\$1,308.00
Short Course registrations	\$1,075.00
Fall meeting registrations	\$795.00
Subtotal registrations	\$1,870.00
<b>TOTAL INCOME:</b>	<b>\$3,178.00</b>
<b>EXPENSES:</b>	
Fall Meeting Costs (Oct-2003)	
Facility, meals	\$755.98
2004 Web site	\$218.95
<b>TOTAL EXPENSES</b>	<b>\$974.93</b>
<b>BALANCE FORWARDED (30-JAN-04)</b>	<b>\$4,244.42</b>

## COURSE ANNOUNCEMENT

**Department of Mathematics-Program in Applied Statistics  
STA531**

**STATISTICAL ISSUES IN THE PHARMACEUTICAL INDUSTRY**

**Summer Session I – 2004, MW 5:45 - 8:30**

This course will introduce students to issues of current importance in the pharmaceutical industry. Topics will include design of clinical trials, sample size determination, bioequivalence, ICH guidelines, computer simulations, sensitivity analysis, missing data, and the drug approval process. It will be open to anyone with an interest in the pharmaceutical industry and a basic knowledge of statistics.

Course Professors:

Mani Y. Lakshminarayanan, Director of Statistics, Centocor, Inc., Malvern, PA

Randall H. Rieger, Associate Professor, West Chester University

For more information, please contact Dr. Rieger at 610-436-2893 [rrieger@wcupa.edu](mailto:rrieger@wcupa.edu).

## ASA COMMITTEES SEEKING NEW MEMBERS

ASA President Elect Fritz Scheuren is about to begin making over 100 appointments and reappointments to the more than fifty ASA committees for terms beginning in 2005. If you are interested in serving on one of these committees, contact ASAP President Charles Tan at [charles\\_tan@merck.com](mailto:charles_tan@merck.com). The committees seeking new members are listed below. Further details on these committees can be found at [www.amstat.org/comm/](http://www.amstat.org/comm/). A description of the committee appointment process is provided in the January 2004 Amstat News. Remember, the continued success of the ASA depends on members, such as you, who perform volunteer work for the association.

### List of ASA Committees Seeking New Members

Joint ASA/AMATYC Committee	Committee on Privacy and Confidentiality
ASA/NCTM Joint Comm on Curriculum in Stats and Probability	Committee on Professional Ethics
ASA/MAA Joint Comm on Undergraduate Statistics	Committee on Publications
ASA/SRCOS So Regional Comm on Statistics Summer Research	Committee on Scientific Freedom and Human Rights
Advisory Committee on Continuing Education	Committee on Statisticians in Defense and National Security
Advisory Committee on Teacher Enhancement	Committee on Statistics and Disability
Committee of Representatives to AAAS	Committee on Women in Statistics
Committee on ASA Archives and Historical Materials	Current Index to Statistics Management Committee
Committee on Applied Statisticians	Deming Lectureship Committee
Committee on Award of Outstanding Statistical Application	Development Committee
Committee on Career Development	E. C. Bryant Scholarship Committee
Committee on Committees	Finance Committee
Committee on Energy Statistics	JABES Management Committee
Committee on Fellows	JCGS Management Committee
Committee on Gay and Lesbian Concerns in Statistics	JEBS Management Committee
Committee on International Relations in Statistics	Noether Award Committee
Committee on Law and Justice Statistics	Samuel S Wilks Memorial Medal Committee
Committee on Meetings	Scientific and Public Affairs Advisory Committee
Committee on Membership Retention and Recruitment	Stats. Partnerships Among Academe, Indust. & Govt. Committee
Committee on Minorities in Statistics	Survey Review Committee
Committee on Nominations	Task Force on the Future of Chance
Committee on Outreach Education	Technometrics Management Committee
	W J Youden Award in Interlaboratory Testing

## 2003 - 2004 ASAP CHAPTER OFFICERS

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