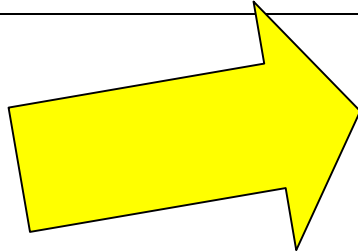


# ASAP Newsletter

The Philadelphia Chapter of the  
American Statistical Association



February, 2005



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

Check it out!

## PRESIDENT'S CORNER

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ASAP welcomed in 2005 with a wonderful **Mid-Winter Gathering!** The event, held at The Sedgeley Club on Boathouse Row, was attended by a capacity crowd who enjoyed good food, conversation and a stimulating talk by Larry Gould. Many thanks to our corporate sponsors -- Tibotec, Merck, GlaxoSmithKline and ICON -- for making this event possible. Thanks also to Paul Johansen, Debbie Panebianco and Paul Lupinacci for their efforts in organizing it.

Our annual **Spring Meeting** will be take place Thursday, March 24 and will feature three outstanding presentations covering a range of topics (see further details on pages 2-4). I hope you will join us for this interesting session – please RSVP by March 18. Your active involvement in our activities is vital to the sustained success of our local ASA chapter.

ASAP is once again sponsoring three awards at the upcoming **Delaware Valley Science Fair** (<http://www.drexel.edu/dvsf/welcome.htm>) on April 6, 2005 at the Fort Washington Expo Center. This program was founded in 1949 and was designed as a vehicle for stimulating interest in science and technology among middle and high school students in the Tri-State area. Please consider participating as an ASAP judge – you may register by contacting an ASAP officer (see page 12) or on-line at <http://www.drexel.edu/dvsf/judging.htm> (be sure to mention you are a “Special Awards” judge with ASAP). See page 5 for additional details.

**Elections** for 2005-2006 ASAP officers are just around the corner, with the following four positions set to expire on June 30, 2005: President, Vice-President, Secretary and Treasurer. Please consider serving ASAP in one of these positions. Details on the election process will be provided in an upcoming newsletter.

We are always eager to hear from our chapter members. If you have recommendations of speakers for future meetings, suggestions of topics for short courses, or ideas for other chapter activities, please feel free to contact any chapter officer. If you are not a member of our local ASAP chapter, please consider joining us! We will have registration information and materials available at the spring meeting. Hope to see you there!

~ Diane Miller

## CALENDAR OF EVENTS

Friday, March 18	Registration deadline for ASAP Spring Meeting
Sun-Wed, March 20-23	ENAR ( <a href="http://www.enar.org">www.enar.org</a> , Austin, TX)
Thursday, March 24	<b>ASAP Spring Meeting, Ft. Washington Holiday Inn</b>
Wednesday, April 6	Delaware Valley Science Fair ( <a href="http://www.dvsf.org">www.dvsf.org</a> )
Sun-Thurs, August 7-11	JSM (Minneapolis): "Using Our Discipline to Enhance Human Welfare"

### ASAP SPRING MEETING

RSVP by **Friday, March 18**

<b>DATE:</b>	<b>Thursday, March 24, 2005, 11:30am-3:30pm</b>	
<b>LOCATION:</b>	Holiday Inn, 432 Pennsylvania Ave, Fort Washington, PA (1-800-339-0209)	
<b>LUNCH DETAILS:</b> <u>Buffet:</u> tossed garden salad with dressings; Caesar salad; antipasto salad; tomato, basil, mozzarella salad; chicken parmigiano; stuffed shells; red potatoes; hot green bean salad; foccacia bread w/olive oil; sliced italian bread; coffee, tea, decaf, iced tea	<b>TIME</b>	<b>PROGRAM</b>
	11:30-noon	<i>Meeting check-in and payment</i>
	noon-1:00	<i>Networking Lunch</i>
	1:00-1:05	<b>Introduction</b> – Diane Miller (President, ASAP)
	1:05 - 1:50	<b>The Distribution of Half-Life of a Drug and Its Median</b> – <i>Liwen Xi (Merck)</i>
	1:50 - 2:35	<b>Statistical Application in the Science of Climate Change</b> – <i>Michael Mann (University of Virginia)</i>
	2:35 - 2:45 2:45 - 3:30	<i>Networking Break</i> <b>Analysis of Repeated Bouts of Measurements in the Framework of Generalized Estimating Equations</b> – <i>Justine Shults (University of Pennsylvania)</i>
<b>Cost:</b> \$30 including lunch; \$15 without lunch and for full-time students.		

**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. The hotel is close to the Ft. Washington SEPTA stop on the R5 Lansdale/Doylestown line ([www.septa.org/service/pdfs/R5LD.pdf](http://www.septa.org/service/pdfs/R5LD.pdf)).

**Registration:** PLEASE REGISTER AND PAY IN ADVANCE by **Friday, March 18** to assist with the head-count. Contact ASAP Treasurer Paul Lupinacci at [paul.lupinacci@villanova.edu](mailto:paul.lupinacci@villanova.edu) / (610) 519-7435, **specifying if you are a student, if you will be eating lunch, if you are an ASA and/or an ASAP member, and your company/institution.** Checks should be made payable to "ASAP" and sent to Paul Lupinacci / Department of Mathematical Statistics / Villanova University / 800 Lancaster Avenue / Villanova, PA 19085.

*Abstract: "The Distribution of Half-Life of a Drug and Its Median"*

In the early phase of a drug development, one of the important pharmacokinetics parameters in clinical pharmacology studies is half-life. The half-life of a drug is the elapsed time for the plasma concentration to fall by one-half. It is perhaps the most easily understood pharmacokinetics parameters, providing a succinct description of many concentration-time profiles. However, statistical aspects of half-life are often overlooked. For example, it is important to assess and compare the half-life between an investigational drug and an existing drug, or between a new formulation and an old formulation. Often, formal statistical analyses are not carried out in the determination of half-life. A common practice is to calculate the harmonic means of a half-life along with jackknife standard deviations. In this paper, the distribution of half-life was studied and the median was proposed to use as a sensible statistical parameter to describe the central tendency of half-life.

*Biosketch*

**Dr. Liwen Xi** received her Ph.D. in 1996 and MS. in 1993 from the Statistics Department at the Pennsylvania State University. She also holds an M.S. in Operations Research from the University of Montana and a B.S. in Mathematics from Fudan University in Shanghai, China. Since joining Merck & Co. in 1996 she has worked in the Vaccine and Clinical Pharmacology groups, working in Phase I-III studies.

*Abstract: "Statistical Application in the Science of Climate Change"*

Dr. Mann will discuss applications of statistical methods to various problems in climate change research. Specific topics to be addressed include the application of multivariate regression methods to reconstructing past climate change from indirect "proxy" indicators such as tree-rings, corals, and ice cores, with applications to the detection of anthropogenic (human-caused) climate change. He will also discuss the application of time-series techniques (in particular, frequency-domain approaches) to the detection of climate signals. Anyone interested in doing some advance reading can read Dr. Mann's July 29, 2003 testimony before the U.S. Senate Committee on Environment and Public Works at [http://epw.senate.gov/108th/Mann\\_072903.pdf](http://epw.senate.gov/108th/Mann_072903.pdf), or read his contributions to Real Climate ([www.realclimate.org](http://www.realclimate.org)), a "commentary site on climate science by working climate scientists for the interested public and journalists."

*Biosketch*

**Dr. Michael E. Mann** teaches in the Department of Environmental Sciences at the University of Virginia. He received undergraduate degrees in Physics and Applied Math from the University of California at Berkeley, an M.S. degree in Physics from Yale University, and a Ph.D. in Geology & Geophysics from Yale University. Current areas of research include paleoclimate data synthesis and statistical climate reconstruction using climate "proxy" data networks, and model/data comparisons aimed at understanding the long-term behavior of the climate system and its relationship with possible external

(including anthropogenic) “forcings” of climate. Other areas of active research include development of statistical methods for climate signal detection, and investigations of the response of geophysical and ecological systems to climate variability and climate change scenarios. Dr. Mann has served as editor for the *Journal of Climate* and has been a member of numerous international and U.S. scientific advisory panels and steering groups. Dr. Mann has been the recipient of several fellowships and prizes, including selection as one of the 50 leading visionaries in Science and Technology by *Scientific American*, the outstanding scientific publication award of the National Oceanographic and Atmospheric Administration (NOAA), and recognition by the Institute for Scientific Information (ISI) for notable citation of his refereed scientific research.

*Abstract: “Analysis of Repeated Bouts of Measurements  
in the Framework of Generalized Estimating Equations”*

We consider a longitudinal study of Interstitial Cystitis (IC) in women in which the time between bouts of repeated measurements is large relative to the within-bout separation in time. Our outcome of interest is the number of 24 hour voids that we model via quasi-least squares (QLS) in the framework of generalized estimating equations (GEE). To account for potential intra-subject correlation we directly apply a correlation structure that previously was only implemented in an ad-hoc approach using GEE. We describe this structure and results of our analysis. We then demonstrate that correct specification of the underlying correlation structure versus incorrectly applying a simpler structure can prevent substantial losses in efficiency in estimation of the regression parameter. These comparisons involve the limiting values of the estimates of the correlation parameters, which are not consistent for the misspecification scenarios considered here. In addition, we compare QLS versus GEE when the banded Toeplitz structure is misspecified as equicorrelated. Because the IC study has a variable number of observations per subject, the losses in efficiency are not identical. They are similar, but slightly smaller for GEE. This is joint work with Carissa A. Mazurick and Richard Landis.

*Biosketch*

**Dr. Justine Shults** received her doctorate in Applied and Computational Mathematics from Old Dominion University in 1996. She is an Assistant Professor of Biostatistics in the Department of Biostatistics at the University of Pennsylvania. Before joining the Biostatistics faculty in 1999, Dr. Shults worked for six years at the Center for Pediatric Research, a joint program of Eastern Virginia Medical School and the Children's Hospital of the King's Daughters in Norfolk, Virginia. While at the Center, she was involved in analyses of data from clinical trials, an NIH-funded program project on human milk, and community based intervention studies. Her collaborations serve as motivational examples for her statistical research in the development of alternative approaches to the analysis of longitudinal data.

Dr. Shults is currently the principal investigator of the NIH funded project "Longitudinal Analysis for Diverse Populations" (R01CA096885). Her work on this project involves quasi-least squares (QLS), which could be viewed as an adjustment to Liang and Zeger's (1986) generalized estimating equation (GEE) approach that yields a different estimate of the correlation parameters.

## DELAWARE VALLEY SCIENCE FAIRS

For the third year in a row, ASAP is looking for a few good judges to help assess student posters at the DVSF on Wednesday, April 6 at the Ft. Washington Expo. Approximately 900 students from the Tri-State area will be competing for awards, prizes and scholarships totaling over \$800,000, as well as a chance to advance to national and international science fairs. Judging will take most of the day, beginning at 7:30am and ending no later than 4:00pm. As in previous years, ASAP will be awarding three prizes, one each to students in the 6<sup>th</sup>-8<sup>th</sup> grades, 9<sup>th</sup>-10<sup>th</sup> grades, and 11<sup>th</sup>-12<sup>th</sup> grades. This year we will be increasing the value of each award from \$100 to \$250, and will also provide winners with JMP IN academic software, generously donated by SAS. This is an excellent opportunity to escape the office to educate a generation of young scientists about the benefits of consulting a friendly neighborhood statistician. We hope interest may be sufficient to participate in DVSF-sponsored mentorships and/or workshops, or -- following the lead of our colleagues in the Harrisburg ASA chapter -- to begin running workshops of our own.

### STATISTICIANS AND ELECTIONS (by Paul Johansen)

*"Democracy is the worst system of governance, except all those other systems which have been tried from time to time." (Winston Churchill)*

Few people in the United States would seriously deny that Democracy is a fine form of government. The backbone of democracy is free and fair elections, in which all eligible individuals are allowed to vote, without hint of coercion, for those people they prefer to represent their interests in the legislative (and occasionally judicial) branches of the government. A legitimate election is one in which "the will of the people" is accurately expressed and measured.

To draw a medical analogy, voters in an election are like participants in a clinical trial: in order to participate it is essential that they be able to provide their informed consent. According to Directive #1 of the Nuremberg Code, "...the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him [*sic*] to make an understanding and enlightened decision."

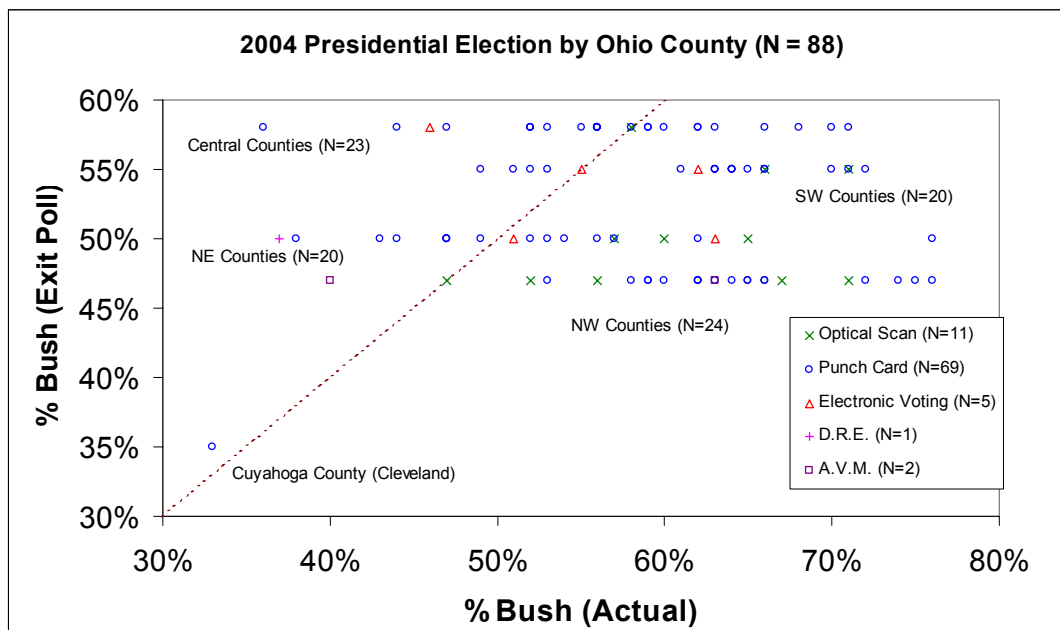
But like any large-scale human endeavor, the process of tallying votes and declaring a winner is far from perfect. In close races, the margin of victory can easily be smaller than the margin of measurement error. Given the statistical nature of elections, we have both a role and a responsibility to ensure that election results are legitimized.

Interestingly, the two agencies hired by the major media outlets to conduct exit polling and predict winners in the Presidential elections of 2000 and 2004, relied less on the skills we have to offer than they might have. When asked how many full-time statisticians the Voter News Service had employed in the 2000 election, I was told that number was zero. In 2004, Joe Lenski of the Edison Media Research/Mitofsky International (EMR/MI) informed me that there were a total of 6-10 people "doing statistical work" on election day. To be fair, people who have spent

their career doing exit poll data collection and analysis may be extremely well versed in statistical practice and/or theory. But this is too important an endeavor to simply assume that the numbers reported are accurate.

Following the 2000 election considerable attention was focused on the state of Florida. In the ensuing legal battles that followed, ASA's 2003 Statistician of the Year, Alan Agresti, served as an expert witness. Although the scrutiny has been less intense following the 2004 election, there have been questions raised about the legitimacy of election results in Ohio, particularly regarding the use of voting technology. According to expert Peter Neumann at the Computer Science Laboratory in Menlo Park, CA, it is technically impossible to create a completely tamper-proof voting machine. Fears of electoral impropriety can easily take root when there is no physical record of each individual's vote -- and thus no possibility of a true recount -- particularly when the manufacturer of widely-used machinery is closely affiliated with one political party.

Below is a summary of Ohio election results by county. Actual and exit poll results were obtained from CNN.com, and the voting technology was provided by Nicole Vicinanza of VoteWatch.us. Unfortunately EMR/MI has been less than forthcoming about its exit poll methodology, and so results are simply presented in five geographic regions covering Ohio's 88 counties. These results do not take population into account, and the relative infrequency of a number of voting technologies do not allow for meaningful assessments of their utility. But a superficial assessment of these results suggests that Bush received a higher percentage of actual election returns than had been predicted based on exit polls. For a more thorough discussion of "The Unexplained Exit Poll Discrepancy" see [www.appliedresearch.us/sf/epdiscrep.htm](http://www.appliedresearch.us/sf/epdiscrep.htm).



*“Although the skills needed to woo voters are at times diametrically opposed to those necessary to govern them, the expensive and arduous [campaign] process exists for a reason: to ensure that those who wish to govern are, if not the most qualified our country has to offer, at least the ones who want it the most.” (Jon Stewart, America: A Citizen’s Guide to Democracy Inaction)*

## EMPLOYMENT

The Philadelphia Chapter of the ASA has over 300 members in a variety of specialties covering academics, industry, and government. We can include your employment advertisement(s) (*maximum 100 words*) in our newsletters for the nominal fee of \$25 per ad. We issue newsletters in September, February, and May. You are encouraged to include the title and a brief description of the position, your contact information, and a link to a web site with additional information. Please send a check -- payable to "ASAP" -- to our Treasurer, and email your text to the Newsletter Editor (see page 12).

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For these three employment opportunities visit [www.iconclinical.com](http://www.iconclinical.com) or contact Kelly Spak / Employment Coordinator / Human Resources / ICON Clinical Research / 212 Church Road / North Wales, PA 19454 / (215) 616-3373 (Direct) / (215) 616-3083 (FAX) / [spakk@iconus.com](mailto:spakk@iconus.com) (no agencies, please) / ICON Clinical Research is an Equal Opportunity Employer committed to strength in diversity.

### **Manager, Clinical Programming**

ICON is seeking a candidate to be responsible for managing the Clinical Programming (SAS) projects within Data Management, Biostatistics, Regulatory Affairs, and other departments. Will also manage staff and provide mentorship, delegate/assign project deliverables, assist with hiring new staff.

Bachelor's degree, appropriate academic postgraduate experience and at least 7 years of Clinical Programming experience required. Experience in managing staff and the ability to interface with clients/management is necessary.

### **Senior Biostatistician**

Responsible for statistical aspects of clinical/pre-clinical research projects including study design, sample size estimation, patient randomization, CRF development, statistical analysis plans, data interpretation, results reporting. Master's or Ph.D. in statistics, biostatistics, or related field with at least 6 years of pharmaceutical or related experience and knowledge in applied parametric/nonparametric statistics, strong SAS programming skills, and the ability to translate client needs into statistical practice and to educate them in the use of statistics are essential. Excellent communication skills required.

### **Senior Biostatistician (Hanover, MD) at GloboMax – The Strategic Pharmaceutical Development Division of ICON**

The selected candidate will support Clinical Phase 1 and Phase 2 Studies. As a member of the project team, you will work closely with representatives of pharmacokinetics, medical affairs, clinical operations, data management, SAS programming, and medical writing departments; will advise on study design and protocol development; and will have primary responsibility to calculate required sample size, provide



validation support for statistical analyses; prepare statistical sections of documents to support NDA or MAA filings; and support clients at regulatory meetings. *Requirements:* Ph.D. in Statistics with 4+ years of experience or M.S. in Statistics with 6+ years of experience; oncology trial experience highly desirable. Strong organizational, problem-solving and communication skills are essential.

**Senior Statistician**

As a Senior Statistician you will participate in preparation of client service proposals; contribute to the protocol development process; prepare statistical analysis plans and mock data displays; apply statistical methods to analyze clinical study data; prepare statistical sections of clinical trial reports; validate summary data displays; prepare material to support client meetings; review protocols, CRFs, analysis plans and study reports, and participate in preparation of proposals. *Requirements:* Ph.D in Statistics with 2+ years of experience or M.S, in Statistics with 4+ years of experience. Strong organizational, problem-solving and communication skills as well as solid knowledge of SAS and familiarity with other statistical software packages are essential.

\* \* \* \* \*

For any of the following 4 employment opportunities, contact **Torey Vizzo** / Managing Director, Biostatistics / The Cambridge Group Ltd / 1175 Post Road East / Westport, CT 06880 / (800) 525-3396 ext. 248 / Fax: (203) 226 - 3856 / [biostat@cambridgegroup.com](mailto:biostat@cambridgegroup.com) / [www.cambridgegroup.com/pharmaceuticals](http://www.cambridgegroup.com/pharmaceuticals)

**Manager/Associate Director, Biostatistics**

Manage all Biostatistical and SAS programming activities for selected projects. Represent Biostatistics on cross-functional and clinical teams. Participate in the preparation of clinical development plans, protocol and CRF design, statistical analysis plans, and database design. Responsible for statistical analysis, interpretation of results, and preparation/review of relevant sections of clinical study reports, NDA summary documents, and other regulatory documents. Manage/oversee work of internal and/or CRO staff. Represent the company in external scientific forums including communication with worldwide regulatory agencies. Provide input into development of internal processes, systems, and SOP's. A PhD with 5-8 years of pharmaceutical experience required.

**Senior Biostatistician/Principal Biostatistician**

Represent the department on Clinical Project Teams for the vaccine area. Responsibilities include the overall statistical support for one or more clinical projects, coordination of the data analysis activities of other staff members and contribution as part of a team working on data analysis and reporting for other projects. Ability to develop new statistical methodologies and actively participate in protocol development are necessary. Requirements: thorough knowledge of the theory and techniques of applied statistical methods such as, experimental designs, ANOVA, linear models, non-parametric, regression,

correlation analysis, categorical data analysis and survival analysis. A PhD with 3+ years of pharmaceutical experience.

### **Senior Biostatistician**

The Senior Research Biostatistician must interact with clinical research personnel, data management and medical writers in the planning, design, conduct, evaluation, interpretation and presentation of study results and reports. Develop and select appropriate statistical methods for design and analysis of studies and projects. Review key project documents and furnish responses on statistical issues raised by regulatory agencies. Serve as department representative on project teams. Candidate must have a PhD with 4 years or a MS with 6 years experience in the pharmaceutical industry.

### **Director, Biometrics**

The Director will manage all Biometrics activities, including the data review and data entry teams. Ensure successful completion of projects; provide statistical/technical guidance to the Biostatistics staff, and programming/technical guidance to SAS programmers; direct the creation of analysis plans, validation protocols and reports. Define Biometrics timelines and resourcing needs; monitor timely compliance for analysis plans, logic checks, data entry audits and analysis; develop SOP and budget proposals; collaborate inter-departmentally to define/solve operations issues; represent clients at FDA meetings. Director must recruit/retain team members while mentoring and providing leadership. A PhD with 8 years of pharmaceutical experience required.

### **COMIC OF THE MONTH**



## TREASURER'S REPORT

**BALANCE FORWARDED (30-Aug-04):**

**\$5,653.02**

**INCOME:**

ASA Chapter Dues			
Jul-04	\$	167.00	
Aug-04	\$	171.00	
Sep-04	\$	160.00	
Oct-04	\$	258.00	
Nov-04	\$	127.00	
	Subtotal Chapter Dues		\$ 883.00
Corporate Sponsorship Mid-Winter Gathering			
GSK	\$	1,000.00	
ICON Clinical Research	\$	500.00	
Merck	\$	1,000.00	
Tibotec	\$	1,000.00	
	Subtotal Corporate Sponsorship		\$3,500.00
Other Revenue Sources			
Fall 2004 Newsletter ads	\$	225.00	
Fall Meeting Registration Fees	\$	765.00	
Mid-Winter Gathering Registration Fees	\$	670.00	
Spring 2005 Newsletter ads	\$	175.00	
	Subtotal Other Revenue Sources		\$1,835.00
<b>TOTAL INCOME:</b>			<b>\$6,218.00</b>

**EXPENSES:**

Fall Meeting expenses (October 2004)			
Facility, meals	\$	772.75	
Speaker Expenses	\$	15.00	
	Subtotal Fall Meeting Expenses		\$ 787.75
Mid-Winter Gathering Expenses (January 2005)			
Sedegley Club	\$	600.00	
Sedegley Club Steward Fee	\$	40.00	
Shackamaxon Caterers	\$	3,510.15	
Supplies	\$	14.52	
	Subtotal Mid-Winter Gathering Expenses		\$4,164.67
Other Expenses			
Bank fees	\$	3.30	
Adjustment	\$	2.00	
	Subtotal Other Expenses		\$ 5.30
<b>TOTAL EXPENSES</b>			<b>\$4,957.72</b>

**BALANCE FORWARDED (01-February-05):**

**[BANK ACCOUNT AND CASH ON HAND(\$22)]**

**\$6,913.30**

## 2004 - 2005 ASAP CHAPTER OFFICERS

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