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# Pooling Community Data for Community Interventions When the Number of Pairs is Small

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#### Introduction

A recent trend in health promotion is the development of interventions that target an entire community, such as communitybased health promotion. Controlled evaluations of such interventions typically compare a group of intervention communities with a group of control communities in terms of reducing the prevalence of an unhealthy behavior, such as smoking. The number of communities has usually been small, for budgetary reasons: 6 for the Minnesota Heart Health Program (3 treatment and 3 control)<sup>i</sup>, just 2 for North Karelia Project <sup>ii</sup> and the Pawtucket Heart Health Program <sup>iii</sup>, and 3 and 5 for two studies at Stanford <sup>iv,v</sup>. Community intervention studies are also described by Shea and Basch<sup>vi</sup>.

An analysis of variance model for a community intervention with 3 communities per treatment group is shown in Table 1, where Y, the dependent variable, is an individual level measure of change. Because the communities were randomized to treatment group, the proper F test is  $F_c$ , which has 1 and 4 degrees of freedom and requires a critical value of 7.71. If the less correct person-level test had been performed,  $F_p$  would have 1 and 598 degrees of freedom, and require a critical value of 3.84. If it were known that  $\sigma^2_b$  was zero,  $F_p$  would have much higher power. A test of significance for whether  $\sigma^2_b$  is zero if  $F_v$ . Note that the procedure effectively uses  $F_c$  when it is least favorable, and uses  $F_p$  when there is no variation and so  $F_c$  would tend to perform well. This perverse sort of cheating will keep the method from performing well.

# [Table 1 about here]

There is some statistical literature describing the use of preliminary tests of significance for pooling mean squares in the analysis of variance.<sup>vii,viii</sup> A major issue is what the  $\alpha$  level of significance should be for the initial test of significance. Bozivich et al.<sup>ix</sup> suggest an  $\alpha$  level of .25 or .50 and the investigator must make some assumption about the variance being zero. Mead et al.<sup>x</sup> recommend that in our situation, the neverpool procedure is best because the potential gain is small while there could be a loss. Wolde et al. <sup>xi</sup> and Donner <sup>xii</sup> also recommend against pooling. However, the analytic and simulation studies that were studied did not consider the configuration that we have, with large degrees of freedom for the residual. For this reason, and because of its importance for community interventions, we decided to study this matter further.

Collection of Biostatistics Research Archive We studied the performance of pooling using simulation. Table 2 defines the terms used in the simulation. Table 3 shows the simulation model. Table 4 describes the simulation process.

[Table 2 and Table 3 and Table 4 about here]

#### Best Case Analysis:

The situation most favorable to the pooling procedure is when  $\sigma_c = 0$ ; that is, there is no community variation, and the person-level test (F<sub>p</sub>) would be appropriate. A low level of  $\alpha$ , such as .05, is favorable because rejection will seldom occur, and the person-level test (F<sub>p</sub>) will usually be performed. We chose N = 500, although it is not obvious whether this is optimal.

[Table 5 about here]

Table 5 shows simulation results for the best case simulation. The first set of simulations has 2 communities per treatment group. The first line shows power for a person-level test, the second for a community-level test, and the third from the pooling procedure.

The treatment effect varies from left to right. When the treatment effect is 0 (the null hypothesis is true) the size is .048 for the person level test, .049 for the community level test, and .046 for the pooled test. Thus, in each case, the size is about 0.05. This should be the case, under the null hypothesis. Note that under the alternative hypothesis, when the effect size is .14, the person-level test has power .882, the community-level test has power .414, and the pooled test has power .837. This is encouraging. The difference between the pooled power and the community level power is .837 - .414 = .423. We call this the "Maximum difference" or "maxdif". If maxdif is not big, there is no point in using the pooling process. Note that in the bottom of the table, for 5 communities per group, maxdif (effect size = .08) is only .09, and it is considerably less than .09 for other parameter combinations. This suggests we limit ourselves to 2, 3, and 4 observations per group. Figure 1 makes this point by plotting maxdif against the number of communities in this best case situation. If we want to gain at least 10 percentage points in power, it makes no sense to look at 5 or more pairs. This is true for 50, 100, or 500 people per community. The lowest line in the graph shows results for N =50,000, which is comparable to a community that can be studied from some external data source that covers all people, such as

surgery rates.

[Figure 1 about here]

Simulation Study for 2, 3, or 4 Pairs.

### Size for K=2.

We next consider the size of the pooled test as a function of  $\alpha_{\text{r}}$  restricting ourselves to N= 2, 3, and 4. Here,  $\sigma_{\text{c}}$  is not zero, and there is no treatment effect.

Figure 2 shows the estimated size of the test as a function of  $\alpha$  for N=2. There are separate lines for different values of N, and values are averaged over several values of  $\sigma_c$ . Size should be .05, since the null hypothesis is true. But, it is substantially above .05 unless  $\alpha = .25$  or .50. These levels were also recommended in the literature. However, since these results are averaged over values of  $\sigma_c$ , there may be some values of  $\sigma_c$  or N in which the pooled test would be advantageous.

[Figure 2 about here]

Figure 3 shows the mean size, again under the null hypothesis, as a function of  $\sigma_c$ , averaged over all values of  $\alpha$ , for different values of N. Note that for low values of  $\sigma_c$ , the size is lower than .05, but that it increases with  $\sigma_c$  and then, in some cases, decreases again. The picture is puzzling, but makes sense. Consider the line for N=1000 people per community. For low  $\sigma_c$  there is almost no community variation, and so the pooled test is approximately correct. For very high values of  $\sigma_c$ , the preliminary hypothesis would almost always be rejected, and the pooled version would again do the right thing. Size is better for small samples than for large samples.

[Figure 3 about here]

Figure 4 shows size as a function of  $\sigma_c$  and  $\alpha$ , averaging over the number of persons per community. Clearly higher values of  $\alpha$  give better control of size, but for low values of  $\sigma_c$  the size is too conservative. The size is acceptable for low  $\sigma_c$ , and high  $\alpha$ .

[Figure 4 about here]

Power Analysis for K=2 : Maximum Difference in Power (Maxdif).

Figure 5 shows maxdif versus  $\alpha$  and N, averaged over  $\sigma_c$ , where maxdif is the maximum difference between the pooled and the community tests in power over all the simulations. Maxdif is highest for moderate values of N (250 or 500) and best for low values of  $\alpha$ .

[Figure 5 about here]

Figure 6 shows maxdif versus  $\sigma_{\rm c}$  for and N, averaged over  $\alpha.$  Power is best for low  $\sigma_{\rm c},$  and moderate N, except for n=50, which is totally different.

[Figure 6 about here]

The above figures have all been for K = 2. Similar figures could be drawn for K=3 and 4, with similar results: there is an extremely complicated relationship between  $\sigma_c$ ,  $\alpha$ , size, maxdif, K, and n. There are some situations in which size was appropriate, but they were not always situations in which maxdif was also high. Because these relationships are so complicated, we decided to look for specific situations in which the pooling method might be helpful. We reasoned that an investigator might we willing to change the pooling method if size and improvement were reasonable.

# Situations in which pooling may be desirable:

Table 6 shows a summary of the simulations for K=2 in which the simulated size was < 6% (close to the nominal 5%). Results are shown as a function of N and  $\alpha$ . For example, for N=50 and  $\alpha$ =.05, the lowest value of  $\sigma_c$  is .000 and the highest is .060. For that range of  $\sigma_c$ , maxdif varied from 10.3 to 13.5 percentage points. Therefore, if one knew that  $\sigma_c$  was .06 or less, pooling could be expected to provide a modest increase in power (10.3 to 13.5 percentage points).

If N=100 and  $\alpha$ =.05, the gain could be as high as 23 percentage points, but  $\sigma_c$  would have to be .02 or less, a more restrictive assumption. In general, the maximum value of  $\sigma_c$  decreases with N, but the potential gain increases with N. As  $\alpha$  increases,  $\sigma_c$  increases somewhat and the percent gain decreases somewhat. The maximum power found (for effect size = .18) is about .10 to .13 for the parameter values considered, so an increase of 10 percentage points could be worth it. It is

unlikely that anyone would choose  $\alpha = .50$  because the gain is so small (even negative for N=50). A value of  $\alpha = .10$  seems reasonable, but .25 is perhaps safer if one is not willing to guess that  $\sigma_c$  is .2 or less.

[Table 6 about here]

Table 7 shows similar results for K=3 communities per group. Pooling might be considered valid using  $\alpha$  = .05 for N <1000 (with if the assumed values of  $\sigma_c$  could be justified) or  $\alpha$  = .10 for N=50 or 100.

[Table 7 about here]

Table 8 shows similar results for K=4 communities per group. One might consider pooling with  $\alpha$  = .05 for N < 1000 if  $\sigma_{\rm c}$  meets the requirements.

[Table 8 about here]

# Empirical Values of $\sigma_{\rm c}$

There are situations in which investigators would benefit from pooling if they knew the value of  $\sigma_{\rm c}$  or at least knew that it was small. We have estimated values of  $\sigma_{\rm c}$  from a variety of data sets, and rarely find values significantly different from zero -- in fact, the estimate is most often zero. However, these estimates are based on small values of K.

We collected a variety of data sets from community interventions, and used a mixed model analysis of variance to estimate  $\sigma^2_{e}$  (variance in smoking among people) and  $\sigma^2_{ct}$  (community by time component of variance)<sup>xiii</sup>. (That is, the data included time as a separate factor, and the dependent variable was a single point in time). We then calculated

$$\sigma_c = \sqrt{\frac{2\sigma_{ct}^2}{\sigma_e^2}}$$

which is equivalent to the value in our simulation in which  $\sigma_e^2$  was 1.0. The variance we usually compute is half the variance of this simulation (because it's a change score).

Collection of Biostatistics Research Archive The data included community interventions on smoking status (9 times, 3 from kaiser); seatbelt use (7 studies, 3 from Kaiser); health status (4 studies, 3 from Kaiser); health status yes/no (4 studies, 3 from Kaiser); dietary fat (3 studies, all from Kaiser).

The distribution of estimates of  $\sigma_{\rm c}$  (adjusted) is:

0	21
00199	1
.020299	4
.030399	2
.040499	0
.050599	3
.060699	1
.1175	1
total	33

Or look at average, by intervention, counting Kaiser only once:

Smoking	.00083 (1/8 non-zero)
HYN	.0124 (2)
Seatbelt	.028 (one huge outlier, BRFS)
Dietary Fat	.006 (1actually average of 3 Kaiser)+1 zero
EVGFP	.0368 (2)
Fiber	.01575 (3 kaiser, 1 eating pattern)

Table 6 suggests that if  $\sigma_c < .06$  and N=50, pooling may be a good idea for any value of  $\alpha$ . Based on these empirical values, it seems safe, since only 1 of the 30 estimates was above .06. Plus, these are empirical, not true variances. It looks as though pooling is "safe" for N=50 for any  $\alpha$ , and for N=100 for some values of  $\alpha$ .  $\sigma_c$  is probably below .2, and almost surely below .07. But there is, unfortunately, one huge outlier. Additional data mayu make the user more confident that the values are usually small.

# Relationship to breaking the matches paper

Power is extremely low for K=2. This seems to disagree with a previous paper <sup>xiv</sup> which said that an unmatched t-test has power .39 when the effect size is 3.0. The first paper did not allow "n" to have any effect, so it's most similar to runs for n =

1000.  $\sigma_{\rm c}$  was effectively 1.0 in that paper, which is very large. An effect size of 3 is  $3\sigma_{\rm c.}$  For 2 pairs, N=1000,  $\sigma_{\rm c}$  =.010, an effect size of .03 would be between .111 and .252. That's a little lower than .39.

## Discussion

It is always preferable to study more communities, but desperate times call for desperate measures. If you must use 2, 3, or 4 pairs communities per group, 3, and 4 pairs, some of these situations may be helpful. Perhaps you can convince yourself that community variation should be small because sugjects were effectively randomized. Otherwise, look at our values of  $\sigma$  and see if they fit your situation. Given the relatively low gain, and the problems inherent in using this method, it is probably not advisable to use pooling in community level trials.



# Table 1 Anova Table

Source	SS	df		df'	MS		EMS		
Due Tx	Ss <sub>a</sub>	1		1	MS <sub>a</sub>		$\sigma_{e}^{2} + n \sigma_{b}^{2} + bn$	$\sigma^2_a$ ?	
Within Tx Among Communities	Ss <sub>b</sub>	2(K-1)	)	4	MS <sub>b</sub>		$\sigma^2_{\ e} + n \ \sigma^2_{\ b}$		
Residual (Person) Ss <sub>r</sub>		2K(n-1)	594	s <sup>2</sup> <sub>e</sub>		$\sigma^2_{e}$			
F-tests:							DF (k=3,n=100)	Value	.05 Crit

Community-level:	$\mathbf{F}_{c} = F_{(1,2(K-1))} = MS_{a}/MS_{b}$	1,4	7.71
Person-level (pooled)	$\mathbf{F}_{p} = F_{2(K-1),2K(n-1)} = MS_{a} / [(SS_{b} + SS_{r}) / (a(Kn-1))]$	1,598	3.84
Test for significant community variation	$\mathbf{F}_{v} = F_{2(K-1),wK(n-1)} = MS_{b} / s_{e}^{2}$	4,594	

Example for K=3, N=100. The pooling process tests whether  $\mathbf{F}_{v}$  is significant at the  $\alpha$  level ( $\alpha$  not necessarily = .05). If significant, test for treatment effect using F<sub>c</sub>. If not F<sub>v</sub> not significant, test for the treatment effect with F<sub>p</sub>.



#### Table 2.

#### Details of Simulation

**K** = # of Communities.

2,3,4 in great detail 5 through 15 in less detail

 $\sigma_{e}^{2}$  = variation among persons within community. (1.0)

**sigc** =  $\sigma_{c}$ , true variation among communities.

Here, the dependent variable is a change score, not the individual values. Its variance is twice as big as the variance of the individual change scores (in a cross-sectional design). So, this variance is twice as big as the variance we usually discuss. (Thanks, ZF)

0,.005,.01, .025, .05, .10, .15, .20, .30

(PFAT is about .06, Fiber is about .03)

Observed community variation is a combination of  $\sigma_{\rm c}$  and  $\sigma_{\rm e}^2/N$ , so it decreases if there are more people per community.

Alpha = probability of type I error when we test whether  $\sigma_c = 0$ . (That is, when we decide whether it's ok to pool).

0,.05,.10,.25,.50

.25 is usually recommended in the literature

In the simulation, we generate a data set, test to decide whether to "pool" (using alpha), then calculate either a person-level or a community-level analysis.

**Size** = percent of time we reject when the null hypothesis (treatment effect is zero) is true. Estimated from simulation.

**Maxdif** = maximum difference in power between the usual (community level) test and the "pooled" test. Estimated from simulation.

Best Case:  $\alpha$  = .05 and  $\sigma_{\rm c}$  =0. That is, there really IS no community-level variation, and we give ourselves the maximum chance to detect it (pool 95% of the time)

COBRA A BEPRESS REPOSITORY Collection of Biostatistics Research Archive Table 3 Simulation Model.

#### Model:

Let  $Y_{ikN}$  be the change score for person N, community K, treatment I

I = 2 tx
K = # of communities/tx
N = # of subjects per community

 $Y_{ikN} \sim N(\mu_{ik}, \sigma_e^2)$ 

Where:

 $\mu_{\text{lk}}$  ~ N (0,  $\sigma_{\text{c}})$ 

```
\mu_{\text{2k}}~\sim~\text{N}~(\Delta,\sigma_{\text{c}})
```

sample means Y<sub>ik.</sub> ~ N( $\mu_{ik}, \sigma^2_e/N$ ) where N = # people/community

So, true change in control communities is zero, <u>on average</u> and true change in treatment communities is  $\Delta$ , on average. If  $\sigma_c = 0$ , then all tx communities have mean 0, all control communities have mean  $\Delta$ . [This is the simulation that was done in the breaking the matches paper --- true?].



#### Table 4 Simulation Process

Choose a value of K,N,  $\sigma_c$ , ( $\sigma_e^2=1$ ), alpha (for pooling test) There are K communities per group. First, generate 2K true means,  $\mu_{ik} \sim N (0, \sigma_c^2)$ Then, generate 2K sample means,  $Y_{ik}$  from N( $\mu_{ik}$ ,  $\sigma_e^2/N$ ) Calculate the variance of the  $\textbf{Y}_{1k.}$  and the  $\textbf{Y}_{2k.}$  - this is MSAThen, generate a MSE value. The true value is 1, based on the model. I don't want to generate a value for each of 500 people per community, so I am generating a MSE separately.  $s_e^2 \sim chi-square / df, df = [IK(N-1)]$ Chi-square ~ ? N[IK(N-1), 2IK(N-1)] So, generate V fom N(IK(N-1),2IK(N-1)), let MSE =  $s_e^2 = V/[IK(N-1)]$ Letting  $\Delta$  vary, calculate Numerator =  $Y_{1k}$  -  $(Y_{2k} + \Delta)$ Person-level denominator =  $s^2/(IKN)$ Community-level denominator = MSA/(2K) Person-level F-test is squared numerator over PLD Community-level F test is squared numerator over CLD Pooled method: (Bad name: call it peek and test?) See if there is significant community variation F = CLD/PLD "large" (p < ALPHA) If F is large, use community-level analysis If F is small, use person-level analysis Change value of  $\Delta$  and repeat Do this 100,000 times. Count number of times the hypothesis is rejected for each value of  $\Delta$  and for each method = "size" or "power".

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# Table 5 best case, N=500 ,alpha=.05

[is N=500 really the best case?]

		POW	ER FOR	2 P	AIRS	10000	ITERA	TIONS		
ALPHA	= .05	N =	500							
				E	FFECT	SIZE -				
SC ME	ETH .O	.02	.04	.06	.08	.10	.12	.14	.16	.18
.000 CON	RS .048 AM .049 DL .046	.059	.087	.128	.189	.257	.335	.414	.497	.572

			POW	ER FOR	3 P	AIRS	10000	ITERA	TIONS		
AL	PHA =	.05	N =	500							
					E	FFECT	SIZE -				
SC	METH	.0	.02	.04	.06	.08	.10	.12	.14	.16	.18
.000	COMM	.054	.072	.140	.250	.386	.778 .542 .742	.688	.813	.899	.947

					4 P.	AIRS	10000	ITERA	TIONS		
ALI	PHA =	.05	N =	500							
					E	FFECT	SIZE -				
SC	METH	.0	.02	.04	.06	.08	.10	.12	.14	.16	.18
.000	COMM	.050	.085	.185	.352	.563	.876 .739 .841	.873	.952	.985	.997

AL	PHA =	.05	-	-	5 P	AIRS	10000	ITERA	TIONS		
					E	FFECT	SIZE -				
SSc	METH	.0	.02	.04	.06	.08	.10	.12	.14	.16	.18
.000	COMM	.053	.105	.245	.464	.694	.940 .867 .917	.955	.989	.998	1.000

AL	PHA =	.05			6 F	PAIRS	10000	ITERA	ATIONS		
	-				E	FFECT	SIZE -				
Sc	METH	.0	.02	.04	.06	.08	.10	.12	.14	.16	.18
.000	PERS	.046	.122	.341	.650	.877	.973	.996	1.000	1.000	1.000
							.936				
.000	POOL	.045	.117	.327	.627	.856	.961	.992	.999	1.000	1.000

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			N		
	50		250	500	1000
ALPHA .05					
SIGCT Minimum Maximum	   .000    .060			   .000  .010	
		.020	.010	010	.010
MAXDIF Minimum Maximum				  41.20  42.25	
.10					
SIGCT					
Minimum	.000				
Maximum	.060	.020	.020	.010	.010
MAXDIF Minimum		 19.60	36 051	   37.15	37 75
Maximum		20.80			38.05
.25					
SIGCT					
Minimum Maximum	.000    .060				
		.000	.010	.0301	.020
MAXDIF Minimum	4.40	13.35	 20.45	  21.45	21.60
Maximum				26.25	
.50					
SIGCT					
Minimum	.000				
Maximum	.060	.060	.060	.060	.050
MAXDIF				1 05	0 05
Minimum Maximum	95    1.80				

# Summary of Simulation Results Size < 6 (2000 replications)

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Summary of Simulation Results Size < 6 and maxdif > 10

	-+		 N		
	++		+	+	
	50   -++	100	250	500   +	1000
ALPHA		l	I	l	
.05					
SIGCT					
Minimum	.000				
Maximum	.050	.040	.020	.020	.010
MAXDIF					
Minimum	8.70				
Maximum	11.65	20.05	21.25	22.40	20.10
.10					
SIGCT					
Minimum	.000				
Maximum	.060	.050	.010	.000	.010
MAXDIF					
Minimum		13.55		17.30	
Maximum	10.05	16.30	17.95	17.30	15.30
.25					
SIGCT					
Minimum	.000				
Maximum	.060	.060	.050	.030	.020
MAXDIF					
Minimum	3.05				
Maximum	4.85	9.05	8.25	8.00	8.15
.50					
			I		
SIGCT Minimum	   .000	  000.	  000	  000.	.000
MINIMUM Maximum	060	.0001			
MAXDIF		1 05	1		
Minimum Maximum	-2.05	-1.05			



Summary of Simulation Results Size < 6 and maxdif > 10

	-+				
	 ++	+	N + <b></b> +	+	
	50	100	250	500	1000
ALPHA .05					
SIGCT	i i	İ		İ	
Minimum	.000	.000	.000	.000	.000
Maximum	.050	.040	.020	.020	.000
MAXDIF					
Minimum		12.35			
Maximum	11.65	13.25	13.80	13.85	13.80
.10					
SIGCT					
Minimum	.000				
Maximum	.060	.040	.010	.010	.010
MAXDIF	· ·				
Minimum Maximum		9.10	9.60		
		10.00	10.20	11.20	10.00
.25					
SIGCT	· ·	l	l	l	
Minimum Maximum	.000    .060				
Haximan		000		000	.000
MAXDIF Minimum	   1.25	 3.15	2.65	 1.70	C (
Maximum	4.05				
.50					
SIGCT		İ		İ	
Minimum Maximum	.000    .060				
MaxLIIIUIII	.000	000.	.000	000.	.000
MAXDIF		1 05			<u> </u>
Minimum Maximum	-2.05	-1.95  50			



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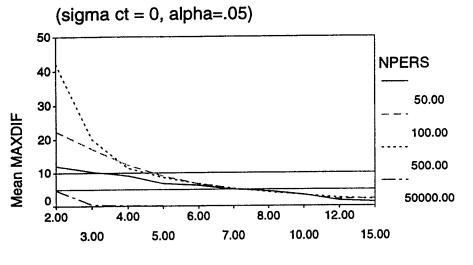
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Figure 1

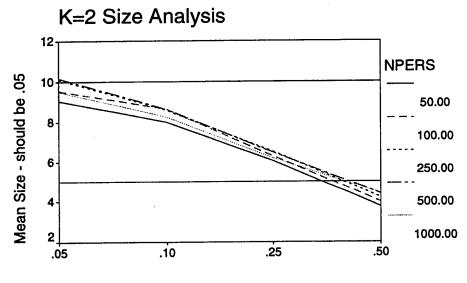
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**Best Case Analysis** 



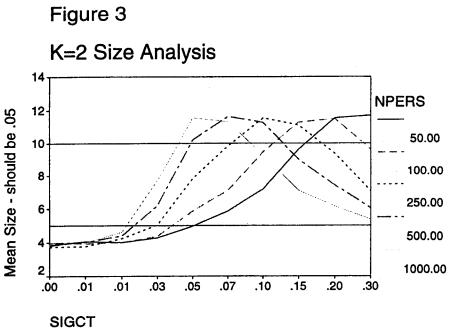
NPAIR

# Figure 2





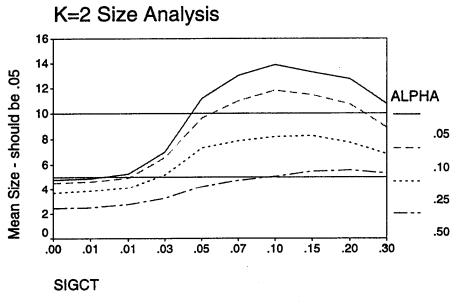
(sigma ct = all, alpha=)





(sigma ct =, alpha= all)

Figure 4



(npers = all)

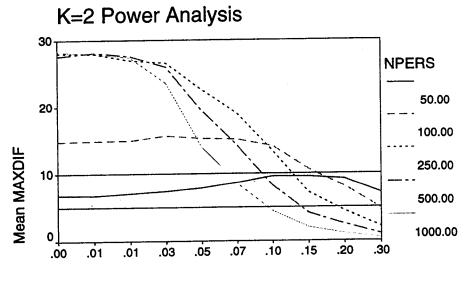
# Figure 5 K=2 Power Analysis 40 **NPERS** 30 50.00 100.00 20 Mean MAXDIF 250.00 10 500.00 1000.00 0 .25 .10 .50 .05



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(sigma ct = all, alpha=)

Figure 6





(sigma ct =, alpha= all)