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# Assessment of Sample Size and Power for the Analysis of Clustered Matched-Pair Data

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# Assessment of Sample Size and Power for the Analysis of Clustered Matched-Pair Data

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## Abstract

This paper outlines how one can determined the sample size or power of a study design that is based on clustered matched-pair data. Detailed examples are provided.

This paper outlines how one can determined the sample size or power of a study design that is based on clustered matched-pair data.

As a review, the following 2 x 2 table is used to summarize the results of a study based on K clusters of matched-pair data:

Procedure 2		Procedure 1		
	Success		Failure	
Success	$\sum_{k=1}^{K} a_k$		$\sum_{k=1}^{K} b_k$	$\sum_{k=1}^{K} (a_k + b_k)$
Failure	$\sum_{k=1}^{K} c_k$		$\sum_{k=1}^{K} d_k$	
	$\sum_{k=1}^{K} (a_k + c_k)$			$\sum_{k=1}^{K} n_k = \mathbf{N}$

 Table 1. McNemar's-Like Table for K Clusters of Matched-Pair Data.

The following table is used to summarize the data for non-clustered matched-pair data:

 Table 2. McNemar's Table for Non- Clustered Matched-Pair Data.

Procedure 2		Procedure 1		
	Success		Failure	
Success	а		b	a+b
Failure	С		d	
				a+b+c+d=N
	a+c			
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#### Procedure to determine sample size of a study design that is based on clustered matched-pair data.

- 1. Initially assume that a non-clustered design will be used.
- Specify the design parameters for the proposed study. 2.
  - a.  $\alpha = 0.05$ , two-sided
    - power = 80%b.
    - c. proportion of matched-pairs with Procedure 1 [Success], Procedure 2 [Success] = 0.03
    - proportion of matched-pairs with Procedure 1 [Success], Procedure 2 [Failure] = 0.07 d.
    - proportion of matched-pairs with Procedure 1 [Failure], Procedure 2 [Success] = 0.02 e.
    - f. proportion of matched-pairs with Procedure 1 [Failure], Procedure 2 [Failure] = 0.88
- Calculate the sample size required for a non-clustered design based on these design parameters (You can use 3. nQuery).
  - Results of nQuery: n (number of matched-pairs) = 262a.
- Next, we need to specify a design parameter associated with the clustered study design: Intra-class correlation 4. (ICC)
  - ICC ( $\rho$ ) is the correlation between pairs of subjects chosen at random from the same cluster. a.

i. 
$$\rho = \frac{\sigma_B^2}{\sigma_B^2 + \sigma_W^2}$$

1. where  $\sigma_B^2$  is the between cluster variability

2. where  $\sigma_w^2$  is the within cluster variability

- b. the size of the ICC is generally larger for smaller clusters
  - i. households  $\sim 0$  to 0.3 (large)
  - ii. postcodes  $\sim 0$  to 0.05 (medium)
  - iii. health districts  $\sim 0$  to 0.001 (small)
  - iv. actual ICC usually not known at the design stage unless you have pilot data or published ICC's.
- 5. Once the ICC is specified, we need to compute the Inflation Factor (IF) aka Design Effect (Deff).
  - The IF (Deff) is a multiplier that tells us how much more the total sample size N needs to be a. increased in order to maintain the design parameters specified in the non-clustered study design (Refer to 2. above).
  - IF = 1 + (n-1)\*ICCb.
    - i. where n = (average sample size per cluster)
      - ii. where ICC is the intra-class correlation
  - c. So even when the ICC is small, the IF is substantial if n is large!
  - When n = 1 (no clustering), IF (Deff) = 1, otherwise > 1. d.
  - The power of a clustered design can be increased when one: e.
    - i. increases the number of clusters (more effective)
      - ii. increases the sample size per cluster (less effective; not much gain in power after 50 subjects per cluster!)

4.63

- Determine the total sample size N required for the clustered design: 6.
  - Compute IF (Deff) a.
    - i. the design parameters specified in 2.a. through 2.f. are used
    - ii. the ICC is assumed to be 0.001, 0.05, 0.3
    - iii. the non-clustered total sample size is 262 (Refer to 3.a. above)
    - iv. the assumed number of clusters is 20 (i.e., average n per cluster is 13.1)
      - 1. IF = 1 + (13.1-1)\*0.32. IF = 1 + (13.1-1)\*0.05=
        - = 1.605
      - 3. IF = 1 + (13.1-1) \* 0.001= 1.0121
  - Compute the total sample size N required for the clustered design b.

i. IF = 4.63, then  $N = 1213.06 = 1214 \rightarrow 93$  clusters of size 13.1

- ii. IF = 1.605, then  $N = 420.51 = 421 \rightarrow 32$  clusters of size 13.1
- iii. IF = 1.0121, then N =  $265.17 = 265 \rightarrow 20$  clusters of size 13.1

## Example of power reduction when the effect of clustering is not accounted for in the sample size.

The design parameters for the proposed study.

$\alpha = 0.05$ , two-sided	
power = 80%	
proportion of matched-pairs with Procedure 1 [Success], Procedure 2 [Success] =	0.03
proportion of matched-pairs with Procedure 1 [Success], Procedure 2 [Failure] =	0.07
proportion of matched-pairs with Procedure 1 [Failure], Procedure 2 [Success] =	0.02
proportion of matched-pairs with Procedure 1 [Failure], Procedure 2 [Failure] =	0.88

The sample size required for a non-clustered design based on these design parameters: n (number of matched-pairs) = 262

The assumed number of clusters is 20 (i.e., average n per cluster is 13.1)

IF = 1 + (13.1 - 1) * 0.3	=	4.63
IF = 1 + (13.1 - 1) * 0.05	=	1.605
IF = 1 + (13.1 - 1) * 0.001	=	1.0121

The total sample size N required for the clustered design if you want to maintain the design parameters specified:

IF = 4.63,	then	N =1213.06 = $1214 \rightarrow 93$ clusters of size 13.1
IF = 1.605,	then	$N=\ 420.51=\ \ 421\rightarrow 32\ clusters\ of\ size\ 13.1$
IF = 1.0121,	then	$N=\ 265.17=\ 265 {\rightarrow}\ 20 \ clusters \ of \ size \ 13.1$

Power of the clustered design if the design parameters are held the same but the IF has not been applied:

ICC= 0.3 (large),	IF = 4.63,	then	Power $= 21\%$
ICC= 0.05 (medium),	IF = 1.605,	then	Power = 57%
ICC= 0.001 (small),	IF = 1.0121,	then	Power $= 79\%$



### References

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Personal Communication from Valerie L. Durkalski (<u>durkalsv@musc.edu</u>) regarding the use of the ICC for sample size determination when considering clustered matched-pair data, June 7, 2004.

