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# A BAYESIAN APPROACH ON SAMPLE SIZE CALCULATION FOR COMPARING MEANS

**Hansheng Wang**
*Guanghua School of Management, Peking University, Beijing, China*

**Shein-Chung Chow**
*National Health Research Institutes, Taipei, Taiwan*

**Murphy Chen**
*StatPlus, Inc., Taipei, Taiwan*

***In clinical research, parameters required for sample size calculation are usually unknown. A typical approach is to use estimates from some pilot studies as the true parameters in the calculation. This approach, however, does not take into consideration sampling error. Thus, the resulting sample size could be misleading if the sampling error is substantial. As an alternative, we suggest a Bayesian approach with noninformative prior to reflect the uncertainty of the parameters induced by the sampling error. Based on the informative prior and data from pilot samples, the Bayesian estimators based on appropriate loss functions can be obtained. Then, the traditional sample size calculation procedure can be carried out using the Bayesian estimates instead of the frequentist estimates. The results indicate that the sample size obtained using the Bayesian approach differs from the traditional sample size obtained by a constant inflation factor, which is purely determined by the size of the pilot study. An example is given for illustration purposes.***

***Key Words:*** Bayesian; Inflation factor; Sample size calculation.

## 1. INTRODUCTION

Sample size calculation plays an important role in clinical research. A too small sample size cannot assure sufficient power for the detection of a clinically meaningful difference, while a too large sample size is an unnecessary waste of the limited resources. Most commonly used sample size calculation procedures are developed from a frequentist perspective. For a comprehensive review of sample size calculation in clinical research, one should refer to Chow et al. (2003b). To perform sample size calculation, information regarding some study parameters are necessarily obtianed. These parameters usually include the population variability and clinically meaningful difference. In practice, however, those parameters are unknown and are usually estimated from literature or some

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Address correspondence to Hansheng Wang, Guanghua School of Management, Peking University, Beijing, China; E-mail: hansheng@gsm.pku.edu.cn

pilot studies. Those estimates are then treated as true parameters. Consequently, it fails to account for the uncertainty induced by the sampling error. As a result, the resulting sample size may not achieve the desired power for detecting a clinically meaningful difference as planned. To account for such an uncertainty induced by the sampling error, a Bayesian approach could be useful.

As indicated by Chow et al. (2003b), sample size calculation is often performed based on either precision or power analysis. Bayesian methods could be applied in both analyses. In practice, we may treat sample size calculation explicitly as a decision problem and employ a loss or utility function. On the other hand, we may focus solely on inference about the parameters. For example, Lindley (1997) suggested that fully Bayesian methods should include the use of a utility function in conjunction with the method by Raiffa and Schlaifer (1961) (for maximization of the expected utility) for determination of the desired sample size. However, Adcock (1988a) indicated that a full Bayesian approach might be difficult to formulate a widely accepted loss or utility function. On the other hand, the idea of estimating the parameters with certain assurance is more appealing, easily understood, and acceptable.

In practice, the objectives of clinical trials could be very different. The primary objective of a given clinical trial could be intended for testing for equality, testing for non-inferiority/equivalence, and/or testing for superiority. The objective of testing for equality is to detect a clinically meaningful difference between a test treatment and a placebo control or an active control. In the pharmaceutical industry, when comparing two drug products for treating patients with the same disease, it may be of interest to test whether the test treatment is superior to an active control agent, which is currently in the marketplace. On the other hand, if the test treatment is less toxic, easy to administer, and/or cheaper, it may be of interest to establish non-inferiority/equivalence between the test treatment and the active control agent in terms of the efficacy endpoints.

Bayesian approaches for sample size calculation have attracted much attention in pharmaceutical (clinical) research and development in the past several decades. For a single normal, mean, Adcock (1988a) developed closed form formulae for the cases with known and unknown variances by averaging the coverage of fixed length posterior credible sets over the predictive distribution of the data. Bayesian sample size estimation for a single binomial parameter has been studied by many authors, for example, Adcock (1988b, 1992, 1995), Pham-Gia and Turkkan (1992), Pham-Gia (1995), and Joseph et al. (1995a,b). Other work related to Bayesian sample size calculation include Goldstein (1981), Spiegelhalter and Freedman (1986), Adcock (1993), Gould (1993), and Hutton and Owens (1993).

Different study objectives result in different statistical hypotheses, which in turn require different statistical testing procedures. As a result, different sample size calculation procedures are necessary for achieving the desired power at the $\alpha$ level of significance. Simon (1999) proposed an alternative Bayesian approach for active control trials by taking into consideration the uncertainty in the degree of effectiveness of the control. In this article, we attempt to develop sample size calculation procedures from a Bayesian's perspective under a commonly used two-arm parallel-group design. The proposed method can be generalized to a standard crossover design (e.g., $2 \times 3$, $2 \times 4$, etc.) without much effort.

The rest of the article is organized as follows. In Section 2, the sample size calculation procedure using a Bayesian approach is derived with noninformative prior. The proposed method is generalized to crossover design in Section 3. An example concerning a hypertension study is carried out to illustrate the proposed Bayesian approach for sample size calculation in Section 4. Finally, a brief discussion is given in Section 5. All proofs are given in Appendix A.

## 2. MAIN RESULTS

Let $x_{ij}$, $i = 1, 2$; $j = 1, \ldots, n_i$, be the observation obtained from the $j$th subject in the $i$th treatment group. Without loss of generality, it is assumed that $n = n_1 = n_2$. It is further assumed that $x_{ij}$s are independent and identically distributed (i.i.d) normal random variables with mean $\mu_i$ and variance $\sigma^2$. The notation $\mathscr{S}$ is used to denote all of the samples.

In practice, the true parameters $\delta = \mu_1 - \mu_2$ and $\sigma$ are usually unknown. Thus, estimators have to be obtained from some pilot studies or subjectively specified by the investigator. In either situation, the knowledge of the underlying true parameter is not perfect and the uncertainty of the specification error is inevitable. To account for such uncertainty, we may consider imposing two improper noninformative priors on $\delta$ and $\sigma^2$, respectively. More specifically, we may assume that $\delta$ follows a uniform distribution on $\mathscr{R}$ and $\sigma^2$ follows a uniform distribution on $\mathscr{R}^+$.

Let $\bar{x}_{i\cdot}$ and $s^2$ be the sample means of the $i$th treatment group and the common sample variance, which are given by

$$\bar{x}_{i\cdot} = \frac{1}{n}\sum_{j=1}^{n} x_{ij} \quad \text{and} \quad s^2 = \frac{1}{2(n-1)}\sum_{i=1}^{2}\sum_{j=1}^{n}(x_{ij} - \bar{x}_{i\cdot})^2 \tag{1}$$

respectively. Thus, we have

$$\hat{\delta} = \bar{x}_1 - \bar{x}_2 \sim N(\delta, \sigma^2\kappa^2)$$
$$\hat{\eta} = d\hat{\sigma}^2 \sim \sigma^2\chi_d^2$$

where $d = 2(n-1)$, $\kappa^2 = 2/n$, and $\eta = d\sigma^2$.

**Theorem 1.** *The posterior distribution of* $(\delta, \sigma^2)$ *can be expressed as*

$$\delta =_d \rho_1\hat{\sigma}t_{d-1} + \hat{\delta} \quad \textit{and} \quad \sigma^{-2} =_d 2\hat{\eta}^{-1}\Gamma(d/2-1)$$

*where* $t_d$ *is a t-random variable with d degrees of freedom,* $\Gamma(d/2-1)$ *is a* $\Gamma$*-random variable with the shape parameter of* $(d/2-1)$*, and* $\rho_1 = \sqrt{2(n-1)/(n(n-2))}$.

It should be noted that $\rho \to 0$ if $\min\{n_1, n_2\} \to \infty$. Therefore, if the sample size involved in the pilot study is sufficiently large, then the posterior distribution of $\delta$ tends to put heavy probability mass around the sample estimate $\hat{\delta}$. In this case, the Bayesian approach developed in this article reduces to the most commonly used frequentist approach. On the other hand, if the sample size of the pilot study is relatively small, the difference could be substantial.

As indicated earlier, the proposed Bayesian sample size calculation formula can be carried out by simply replacing the unknown parameters with

Bayesian estimates in the usual sample size calculation formula. Although Theorem 1 provides specific posterior distribution of the unknown parameters, the corresponding Bayesian estimators still remain unknown. The following theorem is useful for obtaining the Bayesian estimators based on appropriate loss. More specifically, for the location parameter $\delta$, we consider using the most commonly used $L_2$ loss, which is given by $\mathrm{E}[(\delta - \tilde{\delta})^2|\mathscr{S}]$, where $\tilde{\delta}$ represents the corresponding Bayesian estimator. For the scale parameter $\sigma$, we consider obtaining the Bayesian estimator based on the following scale-invariant loss function $\mathrm{E}[(\sigma - \tilde{\sigma})/\sigma|\mathscr{S}]^2$, where $\tilde{\sigma}$ is the corresponding Bayesian estimator. By minimizing the corresponding loss function, the Bayesian estimators for $\mu$ and $\sigma$ can be obtained and are given by the following theorem.

**Theorem 2.** *The Bayesian estimator for $\delta$ and $\sigma^2$ are given by*

$$\tilde{\delta} = \hat{\delta} \quad \textit{and} \quad \tilde{\sigma} = \rho^* \hat{\sigma}$$

*respectively, where* $\rho^* = \rho^* = \sqrt{d/2}\Gamma(d/2 - 0.5)/\Gamma(d/2)$.

As compared with the usual frequentist estimators $\hat{\delta}$ and $\hat{\sigma}^2$, the Bayesian estimator of $\sigma^2$ is inflated $\hat{\sigma}^2$ by a factor of $\rho^*$. This inflation factor reflects the parameter specification uncertainty. Note that $\rho^*$ is purely determined by the sample size used in the pilot study, which decreases to 1 as the sample size goes to infinity. Also, note that the most commonly used sample size calculation formulas are linear functions in terms of $\hat{\sigma}^2$ (see, for example, Chow and Wang, 2001; Chow et al., 2002a,b, 2003a,b,c; Wang and Chow, 2002). Therefore, the Bayesian sample size can be obtained by simply multiplying the traditional sample size by a factor of $\rho^*$. For convenience purposes, the sample size inflation factors with various pilot sample sizes are presented in Table 1 and Fig. 1.

As can be seen from Table 1, when the sample size of the pilot study is too small (e.g., $d < 10$), the sample size obtained by the traditional method needs to be

**Table 1** Sample size inflation factors

| $d$ | $\rho^*$ | $d$ | $\rho^*$ | $d$ | $\rho^*$ | $d$ | $\rho^*$ | $d$ | $\rho^*$ | $d$ | $\rho^*$ |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 6 | 1.151 | 21 | 1.038 | 36 | 1.021 | 51 | 1.015 | 66 | 1.012 | 81 | 1.009 |
| 7 | 1.126 | 22 | 1.036 | 37 | 1.021 | 52 | 1.015 | 67 | 1.011 | 82 | 1.009 |
| 8 | 1.108 | 23 | 1.034 | 38 | 1.020 | 53 | 1.014 | 68 | 1.011 | 83 | 1.009 |
| 9 | 1.094 | 24 | 1.033 | 39 | 1.020 | 54 | 1.014 | 69 | 1.011 | 84 | 1.009 |
| 10 | 1.084 | 25 | 1.031 | 40 | 1.019 | 55 | 1.014 | 70 | 1.011 | 85 | 1.009 |
| 11 | 1.075 | 26 | 1.030 | 41 | 1.019 | 56 | 1.014 | 71 | 1.011 | 86 | 1.009 |
| 12 | 1.068 | 27 | 1.029 | 42 | 1.018 | 57 | 1.013 | 72 | 1.011 | 87 | 1.009 |
| 13 | 1.063 | 28 | 1.028 | 43 | 1.018 | 58 | 1.013 | 73 | 1.010 | 88 | 1.009 |
| 14 | 1.058 | 29 | 1.027 | 44 | 1.017 | 59 | 1.013 | 74 | 1.010 | 89 | 1.009 |
| 15 | 1.054 | 30 | 1.026 | 45 | 1.017 | 60 | 1.013 | 75 | 1.010 | 90 | 1.008 |
| 16 | 1.050 | 31 | 1.025 | 46 | 1.017 | 61 | 1.013 | 76 | 1.010 | 91 | 1.008 |
| 17 | 1.047 | 32 | 1.024 | 47 | 1.016 | 62 | 1.012 | 77 | 1.010 | 92 | 1.008 |
| 18 | 1.044 | 33 | 1.023 | 48 | 1.016 | 63 | 1.012 | 78 | 1.010 | 93 | 1.008 |
| 19 | 1.042 | 34 | 1.023 | 49 | 1.016 | 64 | 1.012 | 79 | 1.010 | 94 | 1.008 |
| 20 | 1.040 | 35 | 1.022 | 50 | 1.015 | 65 | 1.012 | 80 | 1.009 | 95 | 1.008 |

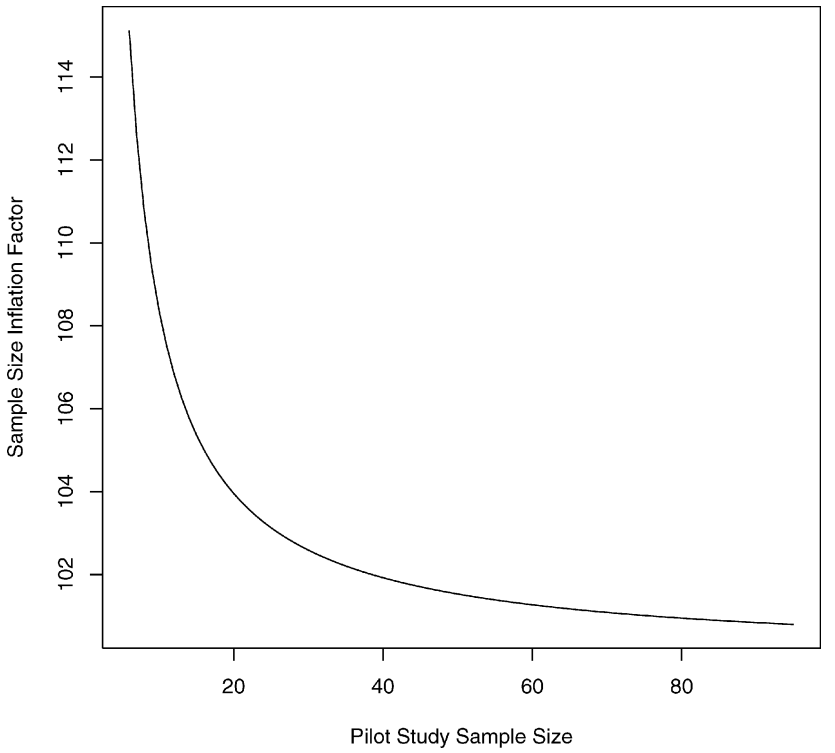


**Figure 1** Sample size inflation factors.

inflated by a factor as large as $1.084^2 = 1.175$. On the other hand, if the sample size in the pilot study is sufficiently large (e.g., $d > 90$), the difference between the Bayesian approach and the frequentist approach is very small ($<1.008^2 = 1.016$).

## 3. CROSSOVER DESIGNS

Although the method was developed primarily based on a parallel group design, its usefulness is not limited to such a situation. For most commonly used crossover designs (e.g., $2 \times 2$, $2 \times 4$, etc), independent estimates of the population mean and variance can also be obtained in a similar way as Eq. (1). By imposing noninformative prior for the population mean difference and the variance of intra-subject comparison (Chow et al., 2003b), similar results can be obtained. For the purpose of simplicity, we use a standard $2 \times 2$ crossover dsign (RT,TR) as an example.

Let $x_{ijk}$, $i = 1, \ldots, n$; $j = 1, 2$; $k = T, R$ be the observation obtained from the $j$th subject in the $i$th sequence under the treatment $k$. Define $c_{ij} = x_{ijT} - x_{ijR}$, the estimate of population mean difference is given by

$$\hat{\delta} = \frac{1}{2n} \sum_{i=1}^{2} \sum_{j=1}^{n} c_{ij} \tag{2}$$

Define the variance of the intra-subject comparison as $\sigma_d^2 = \text{var}(c_{ij})$, which can be estimated by

$$\hat{\sigma}_d^2 = \frac{1}{2(n-1)} \sum_{i=1}^{2} \sum_{j=1}^{n} (c_{ij} - \bar{c}_{i\cdot})^2 \tag{3}$$

where $\bar{c}_{i\cdot}$ is simply the sample average of $c_{ij}$ for the $i$th sequence. As can be seen, the expression of Eqs. (2) and (3) are very similar to Eq. (1). Therefore, by imposing a noninformative prior to the population mean difference $\delta = E(\hat{\delta})$ and the intra-subject comparison variance $\sigma_c^2$, the main results of the last section still follow with appropriate modification to $\kappa$. Therefore, the results of Table 1 are still useful.

## 4. AN EXAMPLE

To illustrate the use of Bayesian approach for sample size calculation described previously, we consider an example concerning a study of hypertension control in elderly patients. The design is a standard two-arm parallel design. A pilot study with a total of 40 patients (20 patients in each arm) was conducted. As a result, $d = 40 - 2 = 38$, which produces a $\rho^* = 1.020$ according to Table 1.

From the pilot study, it is estimated that the mean difference between the treatment and the control is about 24% ($\hat{\delta} = 0.24$) and the variability is about 100% ($\hat{\sigma}^2 = 1.00$). The sample size formula is then performed based on the study objectives of testing for equality, non-inferiority, superiority, and equivalence, respectively. The margin of superiority is assumed to be $\epsilon = 10\%$ and the equivalence margin is assumed to be $\epsilon = 50\%$. Further assume the significance level is 5% and the desired power is 80%. We first obtain the sample sizes using the traditional frequentist approaches (Chow et al., 2003b) as follows:

$$\text{Equality:} \quad n = \frac{2(z_{\alpha/2} + z_\beta)^2 \sigma^2}{\delta^2} = \frac{2(1.96 + 0.84)^2 \times 1.00^2}{0.24^2} = 273$$

$$\text{Superiority:} \quad n = \frac{2(z_\alpha + z_\beta)^2 \sigma^2}{(\delta - \epsilon)^2} = \frac{2(1.64 + 0.84)^2 \times 1.00^2}{(0.24 - 0.10)^2} = 628$$

$$\text{Equivalence:} \quad n = \frac{2(z_\alpha + z_\beta)^2 \sigma^2}{(\epsilon - |\delta|)^2} = \frac{2(1.64 + 0.84)^2 \times 1.00^2}{(0.50 - 0.24)^2} = 181$$

By adjusting the sample size inflation factor $\rho^* = 1.020$, the Bayesian approach gives the following sample size

$$\text{Equality:} \quad 273 \times 1.020^2 = 285$$

$$\text{Superiority:} \quad 628 \times 1.020^2 = 654$$

$$\text{Equivalence:} \quad 181 \times 1.020^2 = 188$$

As can be seen, the Bayesian sample size estimates are consistently larger than those of the traditional approach. The difference could be as large as 4% (superiority). By adopting the Bayesian sample size estimates, it is expected that the parameter specification uncertainty is well-controlled. The validity and integrity of the intended trial is better assured.

## 5. DISCUSSION

In this article, a rather simple but effective Bayesian approach for sample size calculation in clinical trials for comparing treatment means is developed. As compared with the traditional frequentist approach, the Bayesian approach explicitly takes into consideration the sample error involved in parameter estimates from some pilot studies. In addition, the developed approach utilizes a noninformative prior, which avoids the subjective selection of prior parameter specification. As shown, the resulting sample size estimate differs from that of the traditional one by an inflation factor. The inflation factor is always greater than 1 and only depends on the sample size used in the pilot study. Consequently, the method can be easily carried out by first performing the traditional sample size calculation and then adjusting it by a simple inflation factor.

On the other hand, continuous variables are not the only variable of interest in practice. For example, binary and time-to-event type variables are also commonly encountered. Traditional sample size calculation procedure designed for those variables also ignores the uncertainty associated with the pilot estimator. Hence, there is also a need for a Bayesian sample size calculation procedure for those data types. Therefore, further research is definitely needed.

## APPENDIX A

*Proof of Theorem 1.* It can be verified that the joint p.d.f of $(\hat{\delta}, \hat{\eta})$ is given by

$$\left(\frac{1}{\sqrt{2\pi}\sigma\kappa}\right)\exp\left\{-\frac{(\hat{\delta}-\delta)^2}{2\sigma^2\kappa^2}\right\}\frac{\sigma^{-d}}{\Gamma(d/2)2^{d/2}}\exp\left\{-\frac{\hat{\eta}}{2\sigma^2}\right\}$$

It follows that the joint posterior p.d.f of $\delta$ and $\sigma$ is proportional to

$$\sigma^{-d-1}\exp\left\{-\frac{1}{2\sigma^2}\left(\frac{(\hat{\delta}-\delta)^2}{\kappa^2}+\hat{\eta}\right)\right\} \tag{4}$$

By integrating with respect to $\sigma^2$, the marginal posterior p.d.f of $\delta$ is proportional to

$$\left[\frac{(\hat{\delta}-\delta)^2}{\kappa^2}+\hat{\eta}\right]^{-(d-1)/2} \propto \left[\frac{(\hat{\delta}-\delta)^2}{(d-2)\rho_1^2\hat{\sigma}^2}+1\right]^{-(d-1)/2}$$

where

$$\rho_1 = \sqrt{\frac{2(n-1)}{n(n-2)}}$$

Thus, conditional on $\hat{\delta}$ and $\hat{\sigma}^2$, the posterior distribution of $\delta$ can be expressed as

$$\delta|(a,b) =_d \rho_1\hat{\sigma}t_{d-1} + \hat{\delta} \tag{5}$$

which is a location-scale transformed $t$-random variable with $d-1$ degrees of freedom.

On the other hand, according to the joint posterior distribution of $\delta$ and $\sigma^2$ as specified in Eq. (4) and integrated with respect to $\delta$, the posterior distribution of $\sigma^2$ follows a distribution with density proportional to

$$\sigma^{-d} \exp\left\{-\frac{\hat{\eta}}{2\sigma^2}\right\}$$

Consequently, the posterior density of $1/\sigma^2 = s$ is proportional to

$$s^{d/2-2} \exp\left\{-\frac{s\hat{\eta}}{2}\right\}$$

which is a $\Gamma$-distribution with the shape parameter $d/2 - 1$ and the scale parameter $2/\hat{\eta}$. Therefore, the posterior distribution of $1/\sigma^2$ can be expressed as

$$\sigma^{-2} =_d 2\hat{\eta}^{-1}\Gamma(d/2 - 1)$$

This completes the proof.

*Proof of Theorem 2.* As it is well known, under the $L_2$ loss, the Bayesian estimator is the posterior expectation of the parameters. According to Theorem 1, the conditional distribution of $\delta$ can be expressed as

$$\delta = \rho_1 \hat{\sigma} t_{d-1} + \hat{\delta} \tag{6}$$

which implies that $\tilde{\delta} = E(\delta|\mathcal{S}) = \hat{\delta}$. On the other hand, the estimator minimizing the scale invariance loss function $E[(\sigma - \tilde{\sigma})^2/\sigma^2|\mathcal{S}]$ is given by

$$\tilde{\sigma} = \frac{E(\sigma^{-1}|\mathcal{S})}{E(\sigma^{-2}|\mathcal{S})}$$

According to Theorem 1, the posterior distribution of $1/\sigma^2$ is a $\Gamma$-distribution with the shape parameter $d/2 - 1$ and the scale parameter $2/\hat{\eta}$. This leads to

$$\tilde{\sigma} = \frac{\Gamma(d/2 - 1 + 0.5)}{\Gamma(d/2 - 1 + 1)} \times \sqrt{\frac{\hat{\eta}}{2}} = \frac{\sqrt{d}\Gamma(d/2 - 0.5)}{\sqrt{2}\Gamma(d/2)} \times \hat{\sigma}$$

Thus, Theorem 2 follows by defining $\rho^* = \sqrt{d/2}\Gamma(d/2 - 0.5)/\Gamma(d/2)$.

## REFERENCES

Adcock, C. J. (1988a). A Bayesian approach to calculating sample size. *Statistician* 37:433–439.

Adcock, C. J. (1988b). A Bayesian approach to calculating sample size for multinomial sampling. *Statistician* 36:155–159.

Adcock, C. J. (1992). Bayesian approaches to the determination of sample sizes for binomial and multinomial sampling—Some comments on the paper by Pham-Gia and Turkkan. *Statistician* 41:399–404.

Adcock, C. J. (1993). An improved Bayesian procedure for calculating sample sizes in multinomial sampling. *Statistician* 42:91–95.

Adcock, C. J. (1995). The Bayesian approach to determination of sample sizes—Some comments on the paper by Joseph, Wolfson and du Berger. *Statistician* 44:155–161.

Chow, S. C., Wang, H. (2001). On sample size calculation in bioequivalence trials. *J. Pharmacokinetics and Pharmacodynamics* 28:155–169.

Chow, S. C., Shao, J., Wang, H. (2002a). Individual bioequivalence testing under $2 \times 3$ designs. *Stat. Med.* 21:629–648.

Chow, S. C., Shao, J., Wang, H. (2002b). A note on sample size calculation for mean comparisons based on non-central t-statistics. *Biopharm. Stat.* 12:441–456.

Chow, S. C., Shao, J., Wang, H. (2003a). In vitro bioequivalence testing. *Stat. Med.* 22:55–68.

Chow, S. C., Shao, J., Wang, H. (2003b). *Sample Size Calculation in Clinical Research*. New York: Marcel Dekker.

Chow, S. C., Shao, J., Wang, H. (2003c). Statistical tests for population bioequivalence. *Statistica Sinica* 13:539–554.

Goldstein, M. (1981). A Bayesian criterion for sample size. *The Annals of Statistics* 9:670–672.

Gould, A. L. (1993). Sample sizes for event rate equivalence trials using prior information. *Stat. Med.* 12:1209–1223.

Hutton, J. L., Owens, R. G. (1993). Bayesian sample size calculations and prior beliefs about child sexual abuse. *Statistician* 42:399–404.

Joseph, L., Wolfson, D. B., du Berger, R. (1995a). Sample size calculations for binomial proportions via highest posterior density intervals. *Statistician* 44:143–154.

Joseph, L., Wolfson, D. B., du Berger, R. (1995b). Some comments on Bayesian sample size determination. *Statistician* 44:167–171.

Lindley, D. V. (1997). The choice of sample size. *Statistician* 46:129–138.

Pham-Gia, T. G. (1995). Sample size determination in Bayesian statistics—A commentary. *Statistician* 44:163–166.

Pham-Gia, T. G., Turkkan, N. (1992). Sample size determination in Bayesian analysis. *Statistician* 41:389–397.

Raiffa, H., Schlaifer, R. (1961). *Applied Statistical Decision Theory*. Boston: Harvard University Graduate School of Business Administration.

Simon, R. (1999). Bayesian design and analysis of active control clinical trials. *Biometrics* 55:484–487.

Spiegelhalter, D. J., Freedman, L. S. (1986). A predictive approach to selecting the size of a clinical trial, based on subjective clinical opinion. *Stat. Med.* 5:1–13.

Wang, H., Chow, S. C. (2002). A practical approach for parallel trials without equal variance assumption. *Stat. Med.* 21:3137–3151.