Erratum to "CRTFASTGEEPWR: A SAS Macro for Power of Generalized Estimating Equations Analysis of Multi-Period Cluster Randomized Trials with Application to Stepped Wedge Designs"

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Abstract

Whereas the code in the original article (Zhang, Preisser, Li, Turner, and Rathouz 2024) on the implementation of the SAS macro **CRTFASTGEEPWR** accurately produces the included output, the selected parameter values of the marginal mean model expression in Equation (1) for two examples based on a categorical period effects parameterization are considered extreme. This Erratum modifies the original values for period-specific intercepts in the examples with the aim of depicting more typical settings for power calculation in multi-period cluster randomized trials, and to diminish the possibility of errors by users who may be led by the original examples to misinterpret the categorical period effects parameterization in the SAS macro.

Keywords: Erratum.

The period-specific intercepts model

User choice of the categorical period effects option in the SAS macro **CRTFASTGEEPWR** specifies that power calculation for the intervention effect δ is based on the marginal mean model in Equation (1) that has period-specific intercepts

$$g(\mu_{ijk}) = \beta_j + u_{ij}\delta \ , j = 1, \dots, J. \tag{1}$$

For a binary outcome with a logit link function, β_j in Equation (1) corresponds to the log odds of response at the j-th period when $u_{ij} = 0$, which often denotes the control treatment condition. Notably, Equation (1) lacks a 'true' intercept. In contrast, an alternative parameterization to Equation (1) is

$$g(\mu_{ijk}) = \beta_0 + \beta_j + u_{ij}\delta \ , j = 1, \dots, J, \tag{1a}$$

where $\beta_1 = 0$ and β_0 is a 'true' intercept term as it corresponds to a column of ones in the overall design matrix. In Equation (1a), β_0 is log odds of response under the control condition in the first period ($j = 1$) whereas indicator variables for all other periods ($j = 2, \ldots, J$) represent period effects relative to outcome prevalence (for a binary outcome) in the first period. While Equations (1) and (1a) are equivalent with respect to their predicted means μ_{ijk} and interpretation of δ as the period-adjusted intervention effect, understanding their different interpretations for period effects specification is important as it may affect power for testing $H_0 : \delta = 0$.

The original intention of authors in two examples in the article that employ categorical period effects was to specify null or near-null period effects, which could have been accomplished through the specification of equal or nearly equal period-specific intercepts. Rather, in the SAS codes, the selected period-specific intercept value for the first period is very different than the other periods' intercept values. Thus, the outcome proportion under the control condition in the first period is very different from that in other periods, which may not be realistic in most settings. We are concerned that the selection of parameter values for the period-specific intercepts in the two examples, if misunderstood when imitated, could impact the power calculation of users in unintended ways.

In particular, modifications are applied to the SAS code for the third example in the main article and the second example in the appendix, focusing on the parameter values provided for the macro argument concerning categorical period effects. The modifications aim to align these code examples more closely with the model description accompanying Equation (1). The Erratum file has rectified the identified errors using strikethrough and has highlighted their corresponding corrections in green color. While the modifications to the period effects specifications in the two examples had little impact on power as shown below, different period effects specifications could have larger impact on power for the intervention effect in other scenarios.

Corrections to the example from the main article

The third example in the article illustrates power calculation for a cross-sectional stepped wedge cluster randomized trial to improve pre-operative decision-making by the use of a patient-driven question prompt list intervention (Taylor *et al.* 2017; Schwarze *et al.* 2020). In this example, 480 patients enrolled across six periods are clustered within 40 surgeons who are randomized to transition from control (blue cells) to intervention condition (green cells) at one of five randomly assigned sequences (8 surgeons per sequence). We calculate the power for a binary primary outcome regarding whether the patient has a post-treatment regret. We assume a balanced and complete design for the study, 12 patients for each surgeon with two patients in each cluster period. In the marginal mean model for the binary outcome with logit link and average intervention effects model, the control is assumed to have ~~2.2~~ 3 times the odds of reporting post-treatment regret compared to the intervention group, given by $\delta =$ $\cancel{\log(1/2.2) = -0.789}$ $\log(1/3) = -1.099$. The average probability of post-treatment regret at baseline is assumed to be 0.22, such that $\cancel{\beta_0}$ $\beta_1 = \log[0.22/(1-0.22)] = -1.266$ with consistently increasing period effects $\cancel{\beta_i = 0.01, i = 1, \ldots, 5}$ $\beta_j = \beta_{j-1} + 0.01, j = 2, \ldots, 6$. For the working correlation structure, we used the exponential decay correlation structure with ICCs $(\alpha_0, r_0) = (0.03, 0.8)$. Power using the t test and the z test both reach ~~80~~ 78% and are similar to one another considering the moderately large number of clusters.

```
%CRTFASTGEEPWR(alpha = 0.05, m = %str(J(5, 1, 8)), corr_type = ED,
  intervention_effect_type = AVE, delta = -0.789 -1.099,
  period_effect_type = CAT,
  beta_period_effects = %str({-1.266, 0.01,0.01,0.01,0.01,0.01 })
   %str({-1.266, -1.256, -1.246, -1.236, -1.226, -1.216 }),
  alpha0 = 0.03, R0 = 0.8, dist = binary, phi = 1,
  CP_size_matrix = %str(J(5, 6, 2)),
  DesignPattern =%str({0 1 1 1 1 1,
                       0 0 1 1 1 1,
                       0 0 0 1 1 1,
                       0 0 0 0 1 1,
                       0 0 0 0 0 1}));
```

```
  The fast GEE power of binary outcomes with exponential decay correlation
                   structure and (alpha0,r0):(0.03, 0.8)
        Under average intervention effects model and delta = -0.786 -1.099

T  S clusters  df  theta  totaln  Dist     Link   stddel  zpower  tpower
6  5       40  33 -1.266     480  BINARY  LOGIT   2.917   0.8307  0.8081
                   0.01  -1.256                   2.8282  0.8074  0.7835
                   0.01  -1.246
                   0.01  -1.236
                   0.01  -1.226
                   0.01  -1.216
                   0.789 -1.099
```

Corrections to the example from the appendix to the main article

This example illustrates use of the SAS macro **CRTFASTGEEPWR** for a parallel cluster trial, based on the Enforcing Underage Drinking Laws (EUDL) Program (Preisser, Young, Zaccaro, and Wolfson 2003). The EDUL program funded interventions at the community level to enforce laws related to alcohol use by underage persons to reduce the underage drinking. Moreover, the study used a non-randomized trial design because the intervention communities were selected by the administrative units in states. The control communities were selected by the propensity score method to match the intervention communities based on US census data. There are three periods: one baseline assessment and two follow-up assessments for participants in the communities participating in the EUDL program. We will use the design of the EUDL study to calculate the power under the assumption that all confounded covariates were balanced in control and intervention groups. The main outcome is the binary outcome of self-reported last 30-day alcohol use for an underage person. We assume there are 40 clusters in total with 20 clusters per intervention group and 30 participants enrolled in each cluster-period. Assuming the baseline probability of self-reported last 30-day alcohol use for an underage person is 0.6, we set $\cancel{\beta_0}$ $\beta_1 = \log[0.6/(1-0.6)] = 0.405$ with consistently decreasing period effects $\cancel{\beta_1 = 0.01}$ $\beta_j = \beta_{j-1} - 0.01, j = 2, 3$. Under the average intervention effects model, the intervention effect is assumed to decrease the odds of underage drinking by 30% on average, $\delta = \log(0.7) = -0.357$. Moreover, a nested exchangeable correlation structure is used with ICCs $(\alpha_1, \alpha_2) = (0.02, 0.01)$. From the power calculation results, power is close to 90% given the parameters. Thus, this example further illustrates the flexibility of the SAS macro in calculating power for multi-period cluster randomized trials with different designs.

```
%CRTFASTGEEPWR(alpha = 0.05, m = %str(J(2, 1, 20)), corr_type = NE,
  alpha1 = 0.02, alpha2 = 0.01 ,intervention_effect_type = AVE,
  delta = -0.357, period_effect_type = CAT,
  beta_period_effects = %str({0.405,-0.01, -0.01 0.395,0.385}), dist = binary,
  phi=1, CP_size_matrix =  %str(J(2, 3, 30)),
  DesignPattern =%str({0 1 1,
                       0 0 0}));
```

```
 The fast GEE power of binary outcomes with nested exchangeable correlation
                structure and (alpha1,alpha2):(0.02, 0.01)
         Under average intervention effects model and delta = -0.357

T  S  clusters   df  theta  totaln   Dist    Link  stddel  zpower  tpower
3  2        40   36  0.405    3600  BINARY   LOGIT  3.2624  0.9036  0.8875
                     -0.01 0.395                    3.2586  0.903   0.8868
                     -0.01 0.385
                     -0.357
```

We provide SAS codes to calculate and compare powers using GEE analysis bases on different effect sizes. In the example codes, **CRTFASTGEEPWR** is used to calculate powers under varying effect sizes, reducing the odds of underage drinking in the EDUL study by $(20\%, 25\%, 30\%, 35\%, 40\%)$ on average, leading to $\delta = \log(0.20, 0.25, 0.30, 0.35, 0.40) = (-0.223, -0.288, -0.357, -0.431, -0.511)$. Outputs of the SAS codes are attached below the codes.

```
%macro  multi_effectsizes(effectsizes);
  %local index value;
  %do index = 1 %to %sysfunc(countw(&effectsizes,%str( )));
  %let value =%scan(&effectsizes,&index,%str( ));
    %CRTFASTGEEPWR(alpha=0.05, m =%str(J(2,1,20)), corr_type = NE,
      alpha1 = 0.02, alpha2 = 0.01, intervention_effect_type = AVE,
      delta = &value, period_effect_type = CAT,
      beta_period_effects = %str({0.405,-0.01, -0.01 0.395,0.385}), dist = binary,
      phi = 1, CP_size_matrix = %str(J(2, 3, 30)),
      DesignPattern = %str({0 1 1,
                            0 0 0}));
  %end;
%mend;
%multi_effectsizes(-0.223  -0.288 -0.357  -0.431  -0.511);
```

```
 The fast GEE power of binary outcomes with nested exchangeable correlation
                structure and (alpha1,alpha2):(0.02, 0.01)
         Under average intervention effects model and delta = -0.223
```

T	S	clusters	df	theta	totaln	Dist	Link	stddel	zpower	tpower
3	2	40	36	0.405	3600	BINARY	LOGIT	~~2.0482~~	~~0.5352~~	~~0.508~~
				~~-0.01~~ 0.395				2.0322	0.5288	0.5016
				~~-0.01~~ 0.385						
				-0.223						

The fast GEE power of binary outcomes with nested exchangeable correlation structure and (alpha1,alpha2):(0.02, 0.01)
Under average intervention effects model and delta = -0.288

T	S	clusters	df	theta	totaln	Dist	Link	stddel	zpower	tpower
3	2	40	36	0.405	3600	BINARY	LOGIT	~~2.6395~~	~~0.7516~~	~~0.7276~~
				~~-0.01~~ 0.395				2.6373	0.7477	0.7236
				~~-0.01~~ 0.385						
				-0.288						

The fast GEE power of binary outcomes with nested exchangeable correlation structure and (alpha1,alpha2):(0.02, 0.01)
Under average intervention effects model and delta = -0.357

T	S	clusters	df	theta	totaln	Dist	Link	stddel	zpower	tpower
3	2	40	36	0.405	3600	BINARY	LOGIT	~~3.2624~~	~~0.9036~~	~~0.8875~~
				~~-0.01~~ 0.395				3.2586	0.903	0.8868
				~~-0.01~~ 0.385						
				-0.357						

The fast GEE power of binary outcomes with nested exchangeable correlation structure and (alpha1,alpha2):(0.02, 0.01)
Under average intervention effects model and delta = -0.431

T	S	clusters	df	theta	totaln	Dist	Link	stddel	zpower	tpower
3	2	40	36	0.405	3600	BINARY	LOGIT	~~3.9239~~	~~0.9752~~	~~0.967~~
				~~-0.01~~ 0.395				3.934	0.9758	0.9677
				~~-0.01~~ 0.385						
				-0.431						

The fast GEE power of binary outcomes with nested exchangeable correlation structure and (alpha1,alpha2):(0.02, 0.01)
Under average intervention effects model and delta = -0.511

T	S	clusters	df	theta	totaln	Dist	Link	stddel	zpower	tpower
3	2	40	36	0.405	3600	BINARY	LOGIT	~~4.6296~~	~~0.9962~~	~~0.9933~~
				~~-0.01~~ 0.395				4.6605	0.9965	0.9938
				~~-0.01~~ 0.385						
				-0.511						

References

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