

1 **Supplement 1. Simulation-based Assessment of the Distribution of** $d_{jk} = \frac{o_{jk} - i_{jk}}{o_{jk}}$.

2 Recall from Section 2 that to define a ratio that has finite variance, a truncated normal can be used as the data

3 model in Eq. (2) for o_{jk} in $d_{jk} = 1 - \frac{i_{jk}}{o_{jk}}$, which is equal in distribution to $1 - \frac{\mu_{jk}(1 + \delta_{TI}z_1)}{\mu_{jk}(1 + \delta_{TO}z_2)} = 1 - R$,

4 which involves a ratio $R = \frac{(1 + \delta_{TI}z_1)}{(1 + \delta_{TO}z_2)}$ of independent normal random variables z_1 and z_2 (for the case of

5 one measurement per group; multiple measurements per group is treated similarly). Section 2 claimed that

6 provided $\delta_{TO} \leq 0.02$ and $\delta_{TI} \leq 0.05$, the distribution of the truncated version of the ratio $d_{jk} = \frac{o_{jk} - i_{jk}}{o_{jk}}$ is

7 extremely close to a normal distribution.

8

9 Supplement 1 provides 4 example numerical simulation results involving the distribution $(O-I)/O$, with O
 10 assumed to be a truncated normal, with truncation occurring only if O is at least 25 standard deviations from
 11 its mean value. Example 1 is the approximate variance result. Example 2 is a tolerance interval example with
 12 random normal error (no systematic error) for which there is an exact expression for the tolerance interval
 13 coverage factor, so simulation using a normal and a normal divided by a truncated normal can be compared.
 14 Example 3 is example density plots and normal probability plots with error bars showing that $(O-I)/O$ with a
 15 truncated O is approximately normal provided $\delta_{TO} \leq 0.02$. Example 4 investigates the variances of the

16 estimators $\hat{\delta}_R^2$ and $\hat{\delta}_S^2$ that arise from applying ANOVA to $d_{jk} = \frac{o_{jk} - i_{jk}}{o_{jk}}$.

17 **Example S1.1: Approximate variance result for a ratio of a normal to a truncated normal**

18 In R, the # sign denotes a comment. Comments are inserted below in red to explain.

19 `nsim = 10^6; kx = 5; ky = 5. # factors to increase deltaor, deltaos, deltair, deltais`

20 `deltaor = .01*kx; deltaos = .01*kx; deltair = .01*ky; deltais = .01*ky`

21 `deltaot = (deltaor^2+deltaos^2)^.5; deltait = (deltair^2+deltais^2)^.5`

22 `temptrue = 100; N = 100`

23 `temp1 = numeric(nsim); temp2 = numeric(nsim)`

24 `check = matrix(0,nrow=nsim,ncol=2)`

25 `for(isim in 1:nsim) {`

26 `x = temptrue*(1+deltaor*rnorm(N) + deltaos*rnorm(N)) # note N for sys, so 1 obs per group`

27 `x1 = pmax(lboundx,x). # truncation: assume operator measurement is truncated normal`

28 `y = temptrue*(1+deltair*rnorm(N) + deltais*rnorm(N))`

29 `y1 = pmax(lboundy,y) # truncation not necessary for inspector, but does no harm`

30 `temp1[isim] = var((x-y)/x)^.5 # non-truncated version`

31 `temp2[isim] = var((x1-y1)/x1)^.5. # truncated version`

32 `}`

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33 temptot = (deltaor^2+deltaos^2+deltair^2+deltais^2)^.5
34 c(nsim,N,deltaor,deltaos,deltair,deltais,temptot)
35 [1] 1e+06 1e+02 1e-02 1e-02 1e-02 1e-02 2e-02. # approximation is 0.02
36 c(mean(temp1),mean(temp2))
37 [1] 0.01996 0.01996 # actual rounds to 0.02 for untruncated or truncated with 106 simulations
38 c(nsim,N,deltaor,deltaos,deltair,deltais,temptot)
39 [1] 1e+06 1e+02 2e-02 2e-02 2e-02 2e-02 4e-02. # approximation is 0.04
40 c(mean(temp1),mean(temp2))
41 [1] 0.03999 0.03999 # actual via simulation rounds to 0.04 for untruncated or truncated
42 temptot = (deltaor^2+deltaos^2+deltair^2+deltais^2)^.5
43 c(nsim,N,deltaor,deltaos,deltair,deltais,temptot)
44 [1] 1e+06 1e+02 5e-02 5e-02 5e-02 5e-02 1e-01 # exact is 0.10
45 c(mean(temp1),mean(temp2))
46 [1] 0.1011 0.1011 # actual via simulation rounds to 0.10, truncated or not
47 c(nsim,N,deltaor,deltaos,deltair,deltais,temptot)
48 [1] 1e+06 1e+02 1e-01 1e-01 1e-01 1e-01 2e-01. # approximation is 0.20
49 c(mean(temp1),mean(temp2))
50 [1] 0.2118575 0.2118575 # actual rounds to 0.21, so the approximation begins to show error
51 [1] 1.0e+06 1.0e+02 1.5e-01 1.5e-01 1.5e-01 1.5e-01 3.0e-01 # approximation is 0.30 > 0.20
52 c(mean(temp1),mean(temp2),mean(temp3))
53 [1] 0.3587435 0.3587435 # actual rounds to 0.36, which is unacceptably different from 0.30
54
55

```

56 **Example S1.2: Approximate normality of the ratio of a normal to a truncated normal**

57 This example computes a tolerance interval coverage factor using either a normally distributed
58 variate, or a ratio of normal variates in the one-sided normal case. In this one-sided one-group
59 normal case, the exact coverage factor is known analytically (this is the only such case where the
60 exact tolerance interval coverage factor is known analytically). This example is a “bottom-line”
61 normality check in the context of this paper: and essentially the same result is obtained using
62 normal or using a ratio of a normal to a truncated normal. Compare the boldface numbers below (all
63 three are equal to within the simulation error in using a finite but large (10^6) number of
64 simulations). The simulation results reported use $(O-I)/O$ to compute the tolerance intervals in
65 structured data (random and systematic errors).

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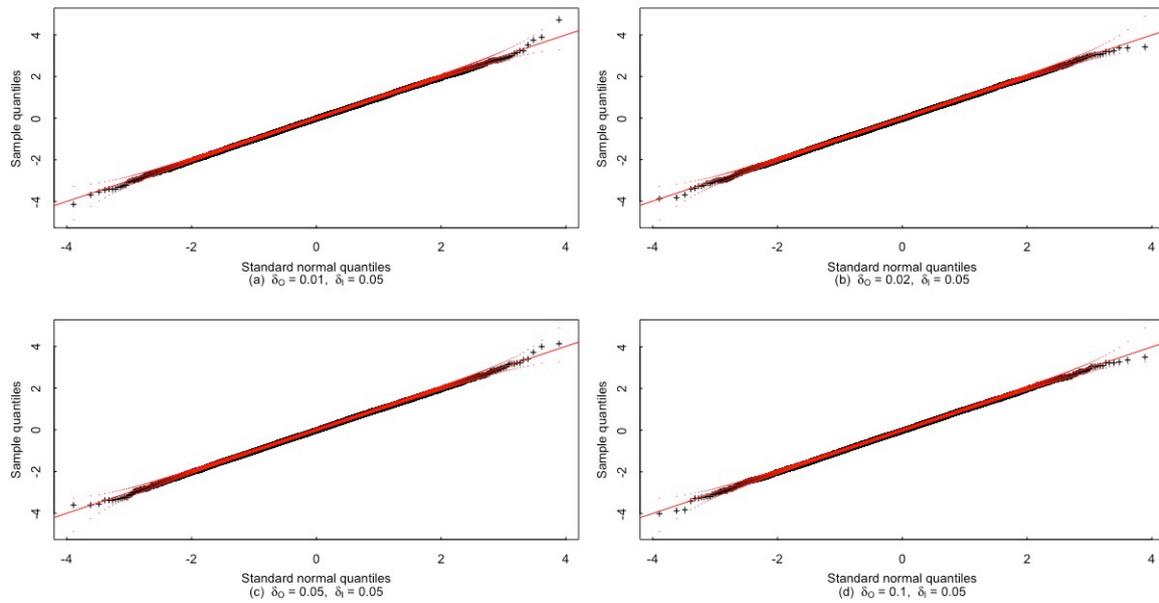
66
67 n1 = 30; p1 = .05; p2 = .01 # p1 is 0.05 coverage, p2 is 99% confidence
68 del = qnorm(p=1-p1)*n1^.5; sd1 = .05;sd2 = .02; tsd = (sd1^2 + sd2^2)^.5
69 nsim = 10^6; mu = 0; k.n = 10^3; kseq = seq(2.3,2.7,length=k.n) # after initial run to zoom kseq
70 tempmat1 <- matrix(0,nrow=nsim,ncol=k.n); tempmat2 <- matrix(0,nrow=nsim,ncol=k.n)
71 for(isim in 1:nsim) {
72   temp1 = mu + rnorm(n=n1,sd=tsd)
73   truncated.normal =pmax(0.5,1+rnorm(n=n1,sd=sd2)) # this truncation will almost never occur
74   temp1a = (1+ rnorm(n=n1,sd=sd1))/truncated.normal
75   temp1a = temp1a-1

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76  temp2 = mean(temp1) + kseq*var(temp1)^.5
77  temp2a = mean(temp1a) + kseq*var(temp1a)^.5
78  tempmat1[isim,] = as.numeric(temp2 >= qnorm(1-p1,sd=tsd))
79  tempmat2[isim,] = as.numeric(temp2a >= qnorm(1-p1,sd=tsd))
80  }
81
82  c(n1,p1,p2,del,sd1,sd2,tsd,nsim)
83  min(kseq[apply(tempmat1,2,mean)>= 1-p2])
84  min(kseq[apply(tempmat2,2,mean)>= 1-p2])
85  #rep1 of 106 simulations
86  c(n1,p1,p2,del,sd1,sd2,tsd,nsim)
87  3.00e+01 5.00e-02 1.00e-02 9.01e+00 5.00e-02 2.00e-02 5.39e-02 1.00e+06
88  min(kseq[apply(tempmat1,2,mean)>= 1-p2])
89  2.516617. # simulation-based, using a normal
90  min(kseq[apply(tempmat2,2,mean)>= 1-p2])
91  2.515015 # simulation-based, using a ratio of a normal to a truncated normal
92  #rep2.of 106 simulations to be sure that 106 is enough simulations to ignore simulation error
93  min(kseq[apply(tempmat1,2,mean)>= 1-p2])
94  2.517417 # simulation-based, using a normal
95  min(kseq[apply(tempmat2,2,mean)>= 1-p2])
96  2.517017# simulation-based, using a ratio of a normal to a truncated normal
97  # exact for 1 sided. # the exact k value is only available for the 1-sided normal tolerance interval
98  del <- qnorm(p=1-p1)*n1^.5
99  # this is k:
100 qt(p=1-p2,df=n1-1,ncp=del)/n1^.5
101 2.515486. # exact, essentially the same as those above from simulation.
102
103
104 Example S1.3: Example normality checks for the ratio
105 A large number (104) observations were simulated from a normal and from a ratio of a normal to a
106 truncated normal. Figures S1.1, S1.2, and S1.3 illustrate that the ratio is extremely close to normal
107 in distribution provided  $\delta_{TO} \leq 0.02$  and  $\delta_{TI} \leq 0.05$ .
108

```

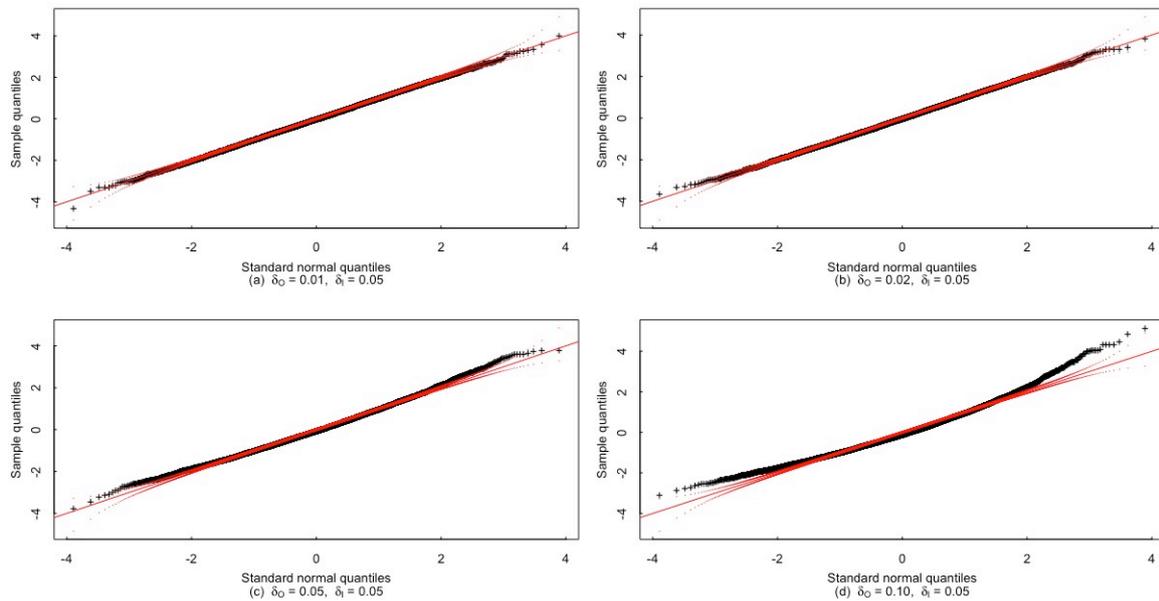


109

110 **Figure S1.1.** Normality checks using normal probability plots and “error bars” (based on
 111 simulation) for a normal random variable using 10^4 observations. As expected, normal data

112 “passes” this normality test. In all plots (Figures a-d), $\delta_{TI} = \sqrt{\delta_{RI}^2 + \delta_{SI}^2} = 0.05$ as an example.

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114

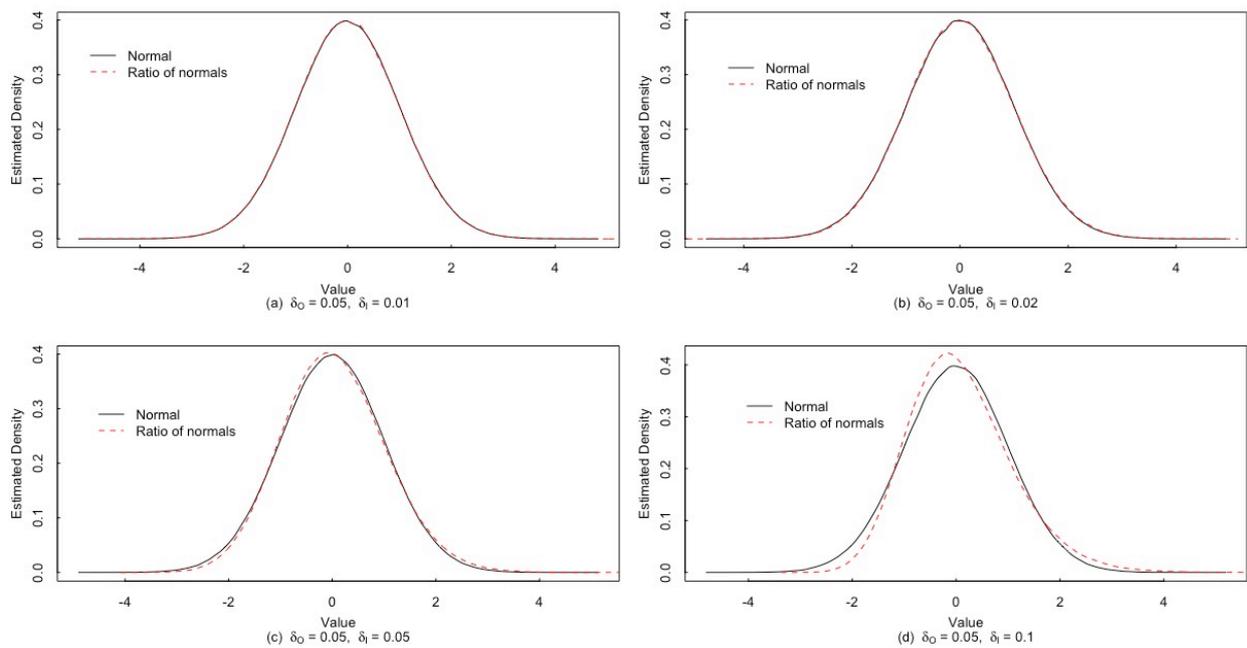
115

116

117 **Figure S1.2.** Normality checks using normal probability plot sand “error bars” for a ratio of a
 118 normal to a truncated normal using 10^4 observations. This ratio data “passes” this normality test

119 provided $\delta_{TO} = \sqrt{\delta_{RO}^2 + \delta_{SO}^2} \leq 0.02$ (top two plots), and begins to show departure from normality

120 if $\delta_{TO} = \sqrt{\delta_{RO}^2 + \delta_{SO}^2} = 0.05$ in these plots with $\delta_{TI} = \sqrt{\delta_{RI}^2 + \delta_{SI}^2} = 0.05$.



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Figure S1.3. The estimated probability density for the same 4 cases as in Figure 2.

125 **Example S1.4. The Variances of the ANOVA-based Estimators $\hat{\delta}_R^2$ and $\hat{\delta}_S^2$**

126 Example 4 investigates the variances of the estimators $\hat{\delta}_R^2$ and $\hat{\delta}_S^2$ that arise from applying

127 ANOVA to $d_{jk} = \frac{o_{jk} - \bar{i}_{jk}}{o_{jk}}$. The point of this example is that it is defensible to assume that

128 $d_{ij} = (o_{jk} - i_{jk})/o_{jk}$ is approximately normal under Eq. (2), with a variance that is well
129 approximately by linear propagation of error variance (Example S1.1), and that the variance of the
130 variance estimates are also well approximated as follows:

131 # columns 1 and 2 are $\hat{\delta}_R^2$ and $\hat{\delta}_S^2$, respectively, for $d_{ij} = (o_{jk} - i_{jk})/o_{jk}$

132 # columns 3 and 4 are $\hat{\delta}_R^2$ and $\hat{\delta}_S^2$, respectively, for $d_{ij} = (o_{jk} - i_{jk})/\square_{jk}$

133 # so, columns 3 and 4 are the same as an additive model, as in standard ANOVA with normal data

134 `nsim = 10^5; check.mat = matrix(0,nrow=nsim,ncol=4)`

135 `for(isim in 1:nsim) {`

136 # simulate 3 groups of 10 measurements per group from Eq. (2):

137 `temp1 =`

138 `generate.data(ngroups=3,nvec=rep(10,3),sigma.r.o=0.01,sigma.r.i=0.01,sigma.s.o=0.005,sigma.s.i=0.01)`

139 # compute d:

140 `dtemp = (temp1[,3]-temp1[,2])/temp1[,2]`

141 # use the usual ANOVA estimates of random and systematic error variances:

142 `temp2 = estvars0(groups=temp1[,1],d=dtemp). # gives same result as lmer() in R`

143 `check.mat[isim,1:2] = temp2[1:2]`

144 `temp1 = generate.data(ngroups=3,nvec=rep(10,3),`

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145 sigma.r.o=0,sigma.r.i=rtotsd,sigma.s.o=0,sigma.s.i=stotsd)
146 dtemp = (temp1[,3]-temp1[,2])/temp1[,2]
147 temp2 = estvars0(groups=temp1[,1],d=dtemp)
148 check.mat[isim,3:4] = temp2[1:2]
149 }
150 # compare approximation to "exact" (nearly exact with 105 simulations)
151 apply(check.mat,2,mean)
152 0.0002001705 0.0001255540 0.0002001561 0.0001255132.
153 # column 1 (ratio) is approximately the same as column 3 (normal) and
154 # column 2 (ratio) is approximately the same as column 4 (normal).
155 stotvar = (.01^2+.005^2); rtotvar = (.01^2+.01^2)
156 c(rtotvar,stotvar)
157 0.000200 0.000125 # agrees with simulation
158
159 apply(check.mat,2,var)^.5
160 5.462549e-05 1.455530e-04 5.468783e-05 1.455614e-04
161 # column 1 (ratio) is approximately the same as column 3 (normal) and
162 # column 2 (ratio) is approximately the same as column 4 (normal).
163 # rep2 of 105 simulations:
164 apply(check.mat,2,mean)
165 0.0001999014 0.0001239302 0.0002000479 0.0001243459
166 apply(check.mat,2,var)^.5
167 5.439924e-05 1.437925e-04 5.456276e-05 1.438669e-04
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```