STUDIECENTRUM VOOR KERNENERGIE

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SAMPLE SIZE REQUIRED TO BE SURE THAT AN INCREASE OF PERCENT DEFECTIVES BY A FACTOR F WILL BE LABELLED «SIGNIFICANT» IN 90 % OF THE CASES

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June 1984

BLG 565

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KEYWORDS: *binomial sampling, sampling design, cost and afficiency, extreme percentages, hypergeometric probability distribution, statistical tables*

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Summary. - A large reference sample of standardly produced items is available.
A new production system is suspected of increasing the proportion of defectives. How much new material do we need to assess an increase by a factor F of the latter with confidence $(1-\alpha)$ and power $(1-\beta)$?
Comparisons are done using hypergeometric distribution.
Tables are given for F = 2 to 12, $\alpha = .05$, $\beta = .10$ and proportions in the reference sample $\hat{P1}$ = .001, .005, .010, .015, .020.

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Résumé. - Un grand échantillon d'éléments obtenus de façon standard est disponible.
Un nouveau système de production est suspecté d'accroître le nombre des défectueux. De quelle quantité de matériel expérimental nouveau avons-nous besoin pour établir que ces derniers ont augmenté d'un facteur F avec un niveau de confiance $(1-\alpha)$ et une puissance $(1-\beta)$?
Les comparaisons sont effectuées à l'aide de la fonction hypergéométrique.
Des tables sont fournies pour F = 2 à 12, $\alpha = .05$, $\beta = .10$ et les proportions suivantes dans l'échantillon de référence $\hat{P1}$ = .001, .005, .010, .015, .020.

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Samenvatting. - Een steekproef van standaard geproduceerde elementen is beschikbaar.
Men vreest dat een nieuw produktiesysteem de verhouding van defekte elementen verhoogt. Hoeveel nieuw materiaal hebben we nodig om een verhoging met een factor F van deze laatsten vast te stellen met een vertrouwensniveau $(1-\alpha)$ en een macht $(1-\beta)$?
De hypergeometrische verdeling wordt gebruikt voor de vergelijking van de verhoudingen.
Tabellen worden gegeven voor F = 2 tot 12, $\alpha = .05$, $\beta = .10$ en verhoudingen in de standaard steekproef $\hat{P1}$ = .001, .005, .010, .015, .020.

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1. INTRODUCTION

Suppose we have studied previously the occurrence of an unfrequent event by examining a large sample (reference sample). Now, we want to study the possible increase of the occurrence of this event resulting from a modification we have introduced. More precisely, we want to detect almost surely (e.g. with .90 certainty) an increase of the rare event by a large factor (e.g. a factor 5) whereas a smaller factor e.g. 1.1 does not interest us (no matter how real it is).

The large reference sample is already at hand or will be obtained first. It is cheap and readily available. The new sample, with the modification present, will take time, money, health or lives and we wish to keep it as small as possible. So, the question is : 'What is the minimum new sample size required to insure protection against a factor F ? '.

2. CASE STUDY

A.) An aeroplane constructor wants to know if a new machine is really worse than the presently used one according to the number of crashes per hour of flight. How many hours should be recorded before one can make sure that there is no increase exceeding F times the old figures ?

B.) A drug D1 is known to produce a few unwished side-effects. A new drug D2 (otherwise satisfactory) is believed to produce much more side-effects. What is the minimum sample size to garantee that an increase -if present- does not exceed a given factor?

C.) One wants to know if a drug could be a teratogen (i.e. cause abnormalities in progeny). Usually, comparison takes place between a treated group and a control group (in all points similar, except for the nature of the product administrated : drug or placebo). Such a strategy looks nice. Practically, owing to limited experimental material, it will never detect any difference, but for the case of an uncommon catastrophe. Precious information can be gained by comparing defectives in stable controls from previous experiments with defectives in the treated group (simultaneous controls are, of course, necessary).

D.) A stable radiation background was measured during a given time. What is the minimum counting time necessary to give us a good chance to detect a radioactivity as large as twice the background ?

(The present approach is apparently sophisticated for problems A. and D. A Kastenbaum -Bowman test (see their paper) is a more natural way. For great samples the two tests give however nearly identical significance levels .)

3.GENERAL SCOPE and RESULTS

As the second sample may be small , we use here throughout an exact test : the tail of the hypergeometric distribution . This test , conditional on the total number of rare events , is commonly used in the analysis of 2x2 tables when the samples are small , but samples do not need to be small to make the test valid (for more detail see for instance Kendall and Stuart(1961) or Owen(1962)) . The use with large samples only requires some care in programming , in order to avoid numerical problems.

Even in somewhat questionable cases where no more than five events were observed in the reference population,one achieves a power not too ridiculously far from the .90 goal-value.

The number of new measurements first drops dramatically when increasing the size of the reference sample but ,at some point, the influence of a further increase of the latter becomes negligible.

It should be pointed out that , due to the lack of continuity, an actual confidence level quite different from the nominal level of the test is often achieved(i.e.tail appreciably smaller than the stated ALPHA value).

When the proportion in the reference group is small enough , the problem has no solution i.e. ,no matter how large the new sample, a power of .90 cannot be achieved . We have then to modify the problem : we can look for more reference data , satisfy ourself with a lower power or decide to perform no experiment at all , since this could not bring us the information we desire. The same is true for F close to 1 .

The sample sizes appearing in the tables suppose , of course , that the exact test and no other will be used in comparing the proportions.

As previously noted in the literature (BRITTEN and SCHLESSELMAN (1982)), it is advisable to use unequal sample sizes, with more data in the group for which the occurrence of the rare events is lowest , even if both type of data are equally expensive (in this case, the benefit is an increased power) .Nevertheless , no adequate aids for sample size determination exist for this type of problem , at least to the author's knowledge.

4. NOTATIONS

N1 : large sample size , fixed

X1 : number of defectives in the large sample size , fixed

$\hat{P1}$ = X1/N1

N2 : small sample size (to be choosen)

X2 : number of defectives in the small sample (will result of the experiment : supposed binomial distributed with parameter P2)

P2(F) = F.$\hat{P1}$: percent defectives we wish to detect with a probability (1 - BETA)

(1-ALPHA) : confidence level used in the test

5. PROCEDURE

N1 , X1 and F are given.
N2 is a trial value for the 'new' sample.
We have a binomial distribution for X2 : BIN (N2,P2=F.$\hat{P1}$).
We can find XS such that for every X2 $\geq$ XS , X2/N2 is significantly higher than X1/N1 , using as test the tail of the hypergeometric distribution(exact test).We adjust N2 so that W = PROB(X2$\geq$ XS) reaches (1-BETA) The dependance of W on N2 is however not continuous: W jumps whenever XS jumps to the next unit . So , two figures are of interest : the smallest N2 for which the probability of detecting a significant increase is at least (1-BETA) and the value N2 such that W$\geq$ (1-BETA) for all larger new sample sizes . The latter has to be used when sample sizes cannot be choosen exactly (e.g. number of foetuses in a teratogenicity study)

6. BIBLIOGRAPHY

WILSON(1984) refers to HALTER(1977) who in turn refers to SCHLESSELMAN (1974) : both samples are planned , the planned samples are equal and the normal approximation is used .

BRITTAIN & SCHLESSELMAN(1982) point out the economical interest of unequal samples. Their aim is an allocation of a total of N measurements, optimally with respect to different criteria .They seem not to be aware of the limits of validity of the normal approximation and indeed use it in cases where it cannot be accepted (the half of the power .31 in Table 3 , line 1 , F=.2 is due to deciding that 1/20 is significantly different from 0/80).

LEMESHOW , HOSMER & STEWART (1981) are aware of shortcomings of the methods commonly used in planning sample sizes for the comparison of very small proportions .They study equal sample sizes determination.

GOULD(1983) wants to take into account the fact that P1 and P2 are only estimated, in planning a new experiment after a pilot experiment giving rough information about both proportions .

HASEMAN(1978) studies the accuracy of the ARCSIN $\sqrt{P}$ method in planning equal sample sizes .

WACHOLDER and WEINBERG(1982) give graphs allowing the estimation of the common sample size needed to achieve a specified power with ALPHA =.05, using an exact test (not interesting for small percentages :sample sizes too small).

WUERGLER and GRAF(1982) give tables based on the Traut's test .This test treats the reference percentage as exactly known.

7.TABLES

Tables 1 and 2 give some illustrations for following observed proportions in the reference sample : .001 , .005 , .010 , .015 , .020
and factors F between 2. and 12.
Table 2 shows that the idea of using unequal samples is not only of academic interest .A drastic reduction in costly measurements can be achieved and even ,in some cases ,the total number of data required may be reduced by a non-negligible amount , notwithstanding the use of an exact method .

8.WARNINGS

1. As $\hat{P1}$ is only estimated , a power of at least .90 is not guaranteed , for a real increase by a factor K = F in population 2 . (The power obtained is .84 for a real increase by a factor 6 , N1=1000 , $\hat{P1}$=.005 and .8735 for a real increase by a factor 8 , N1 = 500 , $\hat{P1}$ = .020 , by repeated use of table 2's second sample size)

Bounds on the real increase K can be obtained as follows.
Let P be the proportion of defectives in sample 1 compared to the total number of defectives :

$$P = P1N1/(P1N1+P2N2) = N1/(N1+KN2)$$

or

$$K = N1/N2 \cdot (1/P - 1) .$$

Confidence limits on $\hat{P}=X1/(X1+X2)$ yield confidence limits on $\hat{K}$.

2. Sizes (N1,N2) are NOT intended for an experiment where sampling will be done BOTH in population 1 and in population 2 .
In such a case, comparison occurs between $\hat{X1}$ /N1 and X2/N2 .
If we limit ourself to the information we have about population 1, $\hat{X1}$ could assume integer values - different from X1- produced by different BIN(N1,PHI) where the spectrum of PHI can be obtained from Bayesian considerations .
For N1 = 5000 , X1 = 5 and N2 = 3549 , the power would be only about .53 in discriminating $\hat{P1}$ from P2 = F.$\hat{P1}$, F = 4.

9. CONCLUSIONS

In number of cases, the maximum possible common sample size for simultaneous measurements provides only a weak basis for comparison of the occurrence of a rare event. This strategy leaves unwished and dangerous situations undetected. While most of the time, a reference value for the standard population is rather well known, this information of good quality is used, at best, for the planning of the experiment. A departure from the usual stable behaviour observed in the 'modified' population and not in the concommitant controls (standard population) would mean early alarm. The sensitivity of the alarm depends on the size of the sample in the 'modified' population. The tables allows the choice of this size for a given sensitivity (factor of increase of the undesirable rare phenomenon). The order of magnitude of the latter remains often feasible while that needed for an equal sample size test is not.

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TABLE 1 - TABULATED : N2 AS A FUNCTION OF N1 , F AND $\hat{P1}$.

N1 : SIZE OF THE REFERENCE SAMPLE
$\hat{P1}$: PERCENTAGE OF DEFECTIVES IN THE REFERENCE SAMPLE
N2 : SAMPLE SIZE REQUIRED IN ORDER TO BE ABLE TO DETECT AN INCREASE OF DEFECTS BY A FACTOR F WITH A PROBABILITY OF AT LEAST .90 , USING AS TEST THE TAIL OF HYPERGEOMETRIC DISTRIBUTION AT THE .95 LEVEL OF SIGNIFICANCE.

NOTE : THE N2 ARE EXACT VALUES . AS THE PROBABILITY OF DETECTION IS NOT A CONTINUOUS FUNCTION OF THE SAMPLE SIZE , A SMALL CHANGE IN N2 CAN INDUCE AN IMPORTANT JUMP IN THE PROB. OF DETECTION . THE LATTER OCCURS WHEN THE CRITICAL NB. OF DEFECTIVES JUMPS TO THE NEXT UNIT .

F	N1 -> 5000	10000	20000
2.	-	-	(>20000)
2.5	-	(11725)	8514
3.	(10148)	5925	4733
4.	3549	2631	2317
6.	1331	1112	1112
8.	834	664	664
10.	531	531	531
12.	442	442	442

$\hat{P1}$ = .001

* : N2 = 8008 <-> PROB. OF DETECT. = .8962

F I V	N1 -->	600	1000	2000	5000	10000
	2.	-	-	-	3716	3042**
	2.5	-	-	(2342)	1511*	1420
	3.	-	(1951)	1183	945	864
	4.	(1062)	708	525	462	462
	5.	518	369	318	318	318
	6.	307	265	221	221	221
	7.	227	190	189	151	151
	8.	166	166	132	132	132
	9.	117	117	117	117	117
	10.	105	105	105	105	105

P1 = .005

* : 1511 <-> PROB. DETECT. = .8987
** : 2921 <-> PROB. DETECT. = .8977

F / V	N1->	500	1000	2000	5000	10000
	2.	-	-	(2078) #	1462##	1349
	2.5	-	(1172)	802	709	661
	3.	(974)	590	471	431	431
	4.	322*	261	230	230	230
	5.	184	158	158	132	132
	6.	132	110	110	110	110
	7.	94	94	75	75	75
	8.	82	65	65	65	65
	9.	58	58	58	58	58
	10.	52	52	52	52	52

Pf = .010

* : 322 <-> .8993 ; NEXT N2 IS 353

\# : 2078 <-> .8998 ; NEXT N2 IS 2134

\#\# : 1462 <-> .8998 ; NEXT N2 IS 1520

N1 ->	600	1000	2000	5000	10000
2.	-	(1751)	1162	936*	860
2.5	(808) #	596	503	440	440
3.	393	340	287	287	260
4.	174	153	153	153	153**
5.	105	105	105	88	88
6.	73	73	73	73	73
7.	62	49	49	49	49
8.	43	43	43	43	43
9.	38	38	38	38	38
10.	34	34	34	34	34

F
|
|
V

PT = .015

\# : N2 = 808 -> PROB. OF DETECT. = .8996 ; NEXT N2 = 839

* : N2 = 896 -> PROB. OF DETECT. = .898

** : N2 = 130 -> PROB. OF DETECT. = .8956

N1 --->	500	1000	2000	5000	6000	10000
2.	(2365) *	(1037) #	757##	673	645	645$
2.5	(560)	400	353	330	330	305$$
3.	274	235	215	194	194	194
4.	130	114	114	114	114	98
5.	78	78	65	65	65	65
6.	54	54	54	54	54	54
7.	46**	37	37	37	37	37
8.	32	32	32	32	32	32
9.	28	28	28	28	28	28
10.	25	25	25	25	25	25

F
|
|
V

$p_1 = .020$

* : N2 = 2365 -> PROB. DETECT. = .8998
** : N2 = 36 -> PROB. DETECT. = .8967
\# : N2 = 1008 -> PROB. DETECT. = .8986
: N2 = 757 -> PROB. DETECT. = .8993; NEXT VALUE = 786
$: N2 = 613 -> PROB. DETECT. = .8965
$$: N2 = 305 -> PROB. DETECT. = .8991

TABLE 2 - TABULATED : N AS A FUNCTION OF N1 , F AND P1

N1 : SIZE OF THE REFERENCE SAMPLE
P1 : PERCENTAGE OF DEFECTIVES IN THE REFERENCE SAMPLE
N : A SAMPLE SIZE N2 > N ALLOWS THE DETECTION OF AN INCREASE OF DEFECTS BY A FACTOR F WITH A PROBABILITY OF AT LEAST .90 , USING AS TEST THE TAIL OF HYPERGEOMETRIC DISTRIBUTION AT THE .95 LEVEL OF SIGNIFICANCE.

NOTE : THERE MAY EXIST SMALLER SAMPLE SIZES FOR WHICH THE DETECTION OCCURS ALREADY IN 90% OF THE CASES BUT THE PROCESS IS NOT CONTINUOUS AND A SMALL VARIATION (EVEN AN INCREASE) OF THE SAMPLE SIZE MAY LEAD TO A DETECTION LEVEL LOWER THAN .90 . FOR A SAMPLE SIZE > N , THE PROBABILITY OF DETECTION IS AND REMAINS > .90 .THE PRESENT TABLE SHOULD BE USED WHEN AN EXACT DETERMINATION OF SAMPLE SIZE IS IMPOSSIBLE AT PLANNING TIME (FOR EXAMPLE : A NUMBER OF ANIMALS TO BE BORN) .

F	N1 -> 5000	10000	20000
	2. -	-	(>20000)
	2.5 -	(>11725)	9439
	3. (>10148)	6707	5530
	4. 4147	3247	2631
V	6. 1544	1331	1331
	8. 834	834	834
	10. 667	531	531
	12. 442	442	442

P1 = .001

	N1 -->	600	1000	2000	5000	10000
	2.	-	-	-	4161	3380
P	2.5	-	-	(2613)	1793	1607
I	3.	-	(2252)	1339	1025	945
I	4.	(1235)	763	587	525	525
V	5.	566	469	369	369	318
	6.	349	307	265	265	221
	7.	263	227	190	189	189
	8.	198	166	166	166	166
	9.	147	147	147	117	117
	10.	132	132	105	105	105

$\hat{P1} = .005$

	N1->	500	1000	2000	5000	10000
	2.	-	-	(2300)	1632	1463
	2.5	-	(1260)	895	756	756
F	3.	(1050)	668	511	471	471
I	4.	383	292	261	261	261
V	5.	209	184	184	158	158
	6.	153	132	131	110	110
	7.	113	94	94	94	94
	8.	82	82	82	82	65
	9.	73	58	58	58	58
	10.	65	52	52	52	52

$\hat{P1} = .010$

F / V	N1 -> 600	1000	2000	5000	10000
	2. -	(1861)	1236**	1012	974
	2.5 (929)	688	565	503	472
	3. 445	366	340	314	314
	4. 194*	194	174	174	174
	5. 122	122	105	105	105
	6. 87	87	73	73	73
	7. 62	62	62	62	62
	8. 54	54	54	54	43
	9. 38	38	38	38	38
	10. 34	34	34	34	34

P1 = .015

* : N2 > 194 -> PROB. OF DETECT. > .90 EXCEPT FOR N2=213 -> .8970

** : N2 > 1236 -> PROB. OF DETECT. > .90 EXCEPT FOR N2=1270 -> .8975
N2=1271
N2=1272 -> .8992

F / V	N1 ---> 500	1000	2000	5000	6000	10000
	2. (2579)	(1148)	842	730	730	701
	2.5 (628)	446	401	354	353	353
	3. 313	255	235	235	235	215*
	4. 145	130	130	114	114	114
	5. 91	78	78	78	78	78
	6. 65	65	54	54	54	54
	7. 46	46	46	46	37	37
	8. 40	40	32	32	32	32
	9. 28	28	28	28	28	28
	10. 25	25	25	25	25	25

$\bar{P1} = .020$

* : EXCEPT 234 -> PROB. OF DETECT. = .8996

TABLE 3 - SAMPLE SIZES (ONE-SIDED TEST - ALPHA = .05 - BETA = .10)

	SCHLESS.	OWEN	EXACT HYPERG.	SAFE HYPERG.
$\hat{P1}$=.005,F=2	N= 5097 2N=10194	N=4956 2N=9912	N1=5000->N2=3716 N1+N2=8716	N1=5000->N2=4161 N1+N2=9161
$\hat{P1}$=.005,F=5	N= 631 2N=1262	N= 554 2N=1108	N1=600->N2=518 N1+N2=1118	N1=600->N2=566 N1+N2=1166
$\hat{P1}$=.010,F=2	N=2528 2N=5056	N=2460 2N=4920	N1=2000->N2=2078 N1+N2=4078	N1=2000->N2=2300 N1+N2=4300
$\hat{P1}$=.010,F=2.5	N=1307 2N=2614	N=1247 2N=2494	N1=1000->N2=1172 N1+N2=2172	N1=1000->N2=1260 N1+N2=2260

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APPENDIX : PROGRAMS

Programs were written in FORTRAN .

- LHYPERG computes the TAIL OF THE HYPERGEOMETIC FUNCTION .

- KASBOWV performs THE KASTENBAUM-BOWMAN TEST.

No numerical problems occured with these routines .
(The KasBow program of Wuergler and Berchtold (1982) gives troubles).

-PLANPROP finds a value of the second sample size for which planned power lies between limits close to .90

-VERIPRO allows the variation by constant steps of the second sample size and shows how the planned power depends on this variation .

-SCHLES computes the common sample size required for detecting ,with a given probability an increase by a given factor R between population 1 and population 2 ,the proportion in population 1 being estimated from a PREVIOUS experience.This previous information will not be used in the test which will compare proportions obtained from the planned EQUAL samples .The NORMAL approximation is used in SCHLES.

-COMPROP is similar to SCHLES except it uses the ARCSIN $\sqrt{P}$ approximation.

THE PROGRAMS CAN BE OBTAINED FROM THE AUTHOR.

ERRATUM to BLG 565

p.6 line 13 : place an asterisk (*) next to 8514.

p.7 line 10 : in column N1=600 and for F=9
the value of N2 is 147 and not 117 as printed.

p.12 line 5 : in column N1 = 1000 and for F=4, N
could be read as 763, it should read 768.

Keywords : cost and efficiency