Dov Tzidony[1] *and Mark Ravreby*[2]

A Statistical Approach to Drug Sampling: A Case Study

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ABSTRACT: In many countries it is left to the discretion of the court to accept or reject conclusions based on sampling procedures as applied to the total drug exhibit. As an alternative to this subjective approach, a statistical basis is presented using binomial and hypergeometric distributions to determine a lower limit for the proportion of units in a population which contains a drug, at a given confidence level. A method for calculating the total weight of a drug present in a population within a given confidence interval is also presented. In the event of no failures (all units sampled contain a drug), a sample size of six or seven units is generally sufficient to state that a proportion of at least 0.70 of the population contains a drug at a confidence level of at least 90%. When failures do occur in the sample, point estimation is used as the basis for selecting the appropriate sample size.

KEYWORDS: toxicology, drug sampling, probability, statistical inference, calculated weight, distribution functions

In Israel the two most common drugs of abuse are heroin and hashish. Street doses of heroin are frequently packaged in small pieces of folded paper, which are further wrapped in plastic, which is heat sealed, making it time consuming to open and weigh the enclosed powder. Mixed legal precedents exist as to whether or not the qualitative result from sampling applies to the total exhibit [*1–3*]. Only one precedent at the district court level exists in Israel regarding the acceptance of the calculated weight of a drug exhibit based on sampling, which was not favorable to the prosecution [*4*]. A recent article on random sampling procedures, focused only on selecting the appropriate sample size, but did not consider calculated weight and point estimation [*5*].

It was decided to change the law in such a way that the qualitative results and calculated weight for the total exhibit based on random sampling, would be evidence as applied to the total exhibit and consequently the burden of proof to contradict this would be shifted to the defendent. This report deals with the statistical basis for the new legislation.

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[1]Reliability Analyst/Chemist, Rafael Haifa, Israel.

[2]Forensic Chemist, Head of Drug Analysis Unit, Division of Criminal Identification, National Police Headquarters, Jerusalem, Israel.

Methodology

Drug Classification

Alleged drug exhibits can be divided into two major classifications according to their source:

(i) drugs from a legitimate manufacturing process.
(ii) drugs from illegal production.

Drugs from the first source include tablets, capsules and solutions. These generally have easily identifiable similar external characteristics such as tablet size, shape, diameter, color, package labelings etc. Since these characteristics greatly enhance the certainty of the identification, it is possible to analyze only one sample purely as a technical confirmation.

Drugs from the second source include "soles" of hashish, paper squares impregnated with L.S.D. and street doses of heroin and cocaine. Although some similar external characteristics may exist which are sufficient to constitute a population for statistical random sampling, their implied identification value is much less than those of drugs from the first source. To a certain degree the classification of a drug exhibit into statistical population(s) must be left to the discretion of the examiner.

Statistical Inference

Two problems are briefly presented below:

(i) Estimating, by random sampling, the proportion of drug units in a drug exhibit.
(ii) Calculating the confidence limits for the total weight of a drug exhibit.

For a more detailed and comprehensive discussion of these issues, the reader is referred to standard statistics textbooks (6 to 11).

Estimating P—*The Proportion of Drug Units in The Population. The Lower Confidence Boundary* P_0 *For* P

If the number of units in the drug exhibit (the total population), exceeds 50, the proportion of drug units—P—is treated as if it were constant during the random sampling process and the binomial distribution is applied. It is desired to show that P is equal or greater than a predetermined value P_0. Hence, for a given sample size n, and an observed number of nondrug units (failures) in the sample r, P_0 must satisfy the following inequality:

$$\sum_{i=0}^{r} \binom{n}{i} P_0^{n-i} (1 - P_0)^i \leq \alpha \tag{1}$$

Where i is the summation index and α is the probability of rejecting the hypothesis $P > P_0$ even though it is true.

In the special case where $r = 0$ (no failures in the sample), Eq 1 reduces to:

$$P_0^n \leq \alpha \tag{2}$$

Using equation (2) Table 1 shows the confidence level $1 - \alpha$ as a function of sample size n and P_0, the lower limit for the proportion of drug units in the population.

TABLE 1—*Confidence level (1 − α) as a function of sample size (n) and the lower limit of the proportion of drugs in the population (P_0) (all sample units containing a drug), using binomial distribution.*

	P_0		
n	0.7	0.8	0.9
5	0.83	0.67	0.41
6	0.88	0.74	0.47
7	0.92	0.79	0.52
10	0.97	0.89	0.65
15	0.99	0.96	0.79

Using equation (1) Table 2 shows P_0 as a function of sample size n and the number of nondrug units r (r = 0 to 5) at a confidence level of at least 90%.

A disadvantage of applying the binomial distribution to drug sampling is its inaccuracy when applied to relatively small populations (≤50). In such cases the proportion P keeps changing throughout the sampling process, and treating it as constant may introduce significant errors. The parameter P is discrete having values of the form:

$$0,\ 1/N,\ 2/N,\ 3/N \ldots\ldots N/N$$

where N is the population size.

The appropriate distribution to use is the hypergeometric distribution. The lower limit for P is $K_0/N = P_0$ where K_0 is the maximum number of drug units in the population which satisfies the following inequality:

$$\sum_{i=0}^{r} \frac{\binom{K_0}{n-i}\binom{N-K_0}{i}}{\binom{N}{n}} \leq \alpha \tag{3}$$

The probability of rejecting the hypothesis $P > K_0/N$, even though it is correct depends on the true value of P. The parameter α is the maximum value of this probability. In

TABLE 2—*The lower limit for the proportion of drug units in the population (P_0), as a function of sample size (n) and the number of failures (r) (sample units not containing a drug) at a confidence level 1 − α = 90% using binomial distribution.*

	r					
n	0	1	2	3	4	5
5	0.63	0.42	0.25	0.11	0.02	—
6	0.68	0.49	0.34	0.20	0.09	0.02
7	0.72	0.55	0.40	0.28	0.17	0.08
10	0.79	0.68	0.55	0.45	0.35	0.27
15	0.85	0.75	0.66	0.57	0.50	0.40
20	0.89	0.81	0.74	0.67	0.61	0.54
30	0.92	0.87	0.83	0.78	0.74	0.69

the special case where $r = 0$ (all units sampled contained a drug) equation (3) reduces to:

$$\frac{K_0!\,(N-n)!}{N!\,(K_0-n)!} \leq \alpha \tag{4}$$

Using equation (4) Table 3, analogous to Table 1 (binomial), shows the confidence level $1 - \alpha$ as a function of sample size n, population size N, and the lower limit for the proportion of drugs in the population P_0.

Comparison of Tables 3 and 1, shows that as N gets larger $1 - \alpha$ of the hypergeometric distribution gets smaller, approaching $1 - \alpha$ of the binomial distribution. Thus, for example, the difference between $1 - \alpha$, in Table 3, for $P_0 = 0.7$ and $N = 50$, and $1 - \alpha$ in Table 1 for $P_0 = 0.7$, is small (less than 0.02). This small difference justifies using the binomial distribution with population sizes exceeding 50. It is clear that using the binomial tables for small populations introduces an error of underestimating the confidence level or overestimating the sample size required for a given statistical statement.

In Table 4, P_0 is presented as a function of sample size (n), population size (N) and observed number of failures r at $1 - \alpha = 90\%$. When applying Eq 3 one solves for K_0, which is an integer. However, for easier comparison of the results from Table 4 with Table 2, K_0 values are presented as the proportion P_0.

Due to integer round off limitations which are exacerbated with smaller populations, care must be exercised in interpolating results from Tables 3 and 4. Multiples of ten were deliberately chosen as values for N in Tables 3 and 4 to minimize some of these problems and make it easier to see trends in the data.

When the number of negatives observed in the sample is equal or less than that

TABLE 3—*Confidence level ($1 - \alpha$) as a function of the lower limit of the proportion of drugs in the population (P_0), the population size (N) and the sample size (n) (all sample units containing a drug), using hypergeometric distribution.*

n \ N	$P_0 = 0.7$					$P_0 = 0.8$				
	10	20	30	40	50	10	20	30	40	50
5	0.92	0.87	0.86	0.85	0.847	0.78	0.72	0.70	0.697	0.69
6	0.97	0.92	0.91	0.90	0.895	0.87	0.79	0.77	0.765	0.758
7	0.99	0.96	0.94	0.93	0.933	0.93	0.85	0.83	0.82	0.81
10	—	0.99	0.98	0.985	0.982	—	0.955	0.93	0.924	0.917
15	—	—	≈1.0	0.999	0.998	—	0.999	0.992	0.986	0.982

TABLE 4—*The lower limit for the proportion of drugs in the population (P_0), as a function of sample size (n), population size (N) and the number of failures in the sample (r) (sample units not containing a drug), with a confidence level $1 - \alpha \geq 90\%$, using hypergeometric distribution.*

n \ N	$r = 0$			$r = 1$			$r = 2$			$r = 3$		
	20	30	40	20	30	40	20	30	40	20	30	40
5	0.65	0.63	0.65	0.45	0.43	0.43	0.25	0.27	0.25	0.10	0.10	0.10
10	0.85	0.80	0.80	0.70	0.70	0.68	0.60	0.57	0.58	0.50	0.47	0.48
15	0.90	0.87	0.88	0.80	0.80	0.78	0.75	0.70	0.70	0.65	0.63	0.63

anticipated, random sampling procedures were considered to be reasonable if they satisfied the following criteria:

$$P_0 \geq 0.70$$

$$1 - \alpha \geq 90\%$$

If no negatives were observed in the sample (all the units in the sample contained a drug), these criteria are met for a sample size of 5, 6 or 7.

The Point Estimate for P

The point estimate for P—the proportion of drug units in the population is $\hat{P}$—the proportion of drug units found in the sample. The standard deviation for the point estimate is evaluated as follows:

$$S_{\hat{p}} = (\hat{P}(1 - \hat{P})/n)^{0.5} \tag{5}$$

By setting the first derivative to zero and solving for $\hat{P}$ it is found that the standard deviation has a maximum value when:

$$\hat{P} = 0.5$$

or, in other words, when 50% of the sample contains drug units. An important factor to consider in determining the sample size is maintaining the standard deviation (a dispersion measure) of the point estimate $\hat{P}$ within a reasonably low limit, for example, $S_{\hat{p}} = 0.1$. Other factors are the value of $\hat{P}$ and the population size. Based on these criteria the data in Table 5 were calculated. When the sample size $n \geq 30$, the normal approximation can be used to determine a lower confidence limit for P at a confidence coefficient $1 - \alpha$ using the following inequality:

$$P \geq \hat{P} - Z_{1-\alpha} S_{\hat{p}} \tag{6}$$

Calculated Weight of The Drug Exhibit

It is assumed that the weight of a single unit is a normally distributed random variable. Since the sample size is a relatively small number it is more appropriate to use the t distribution (as opposed to normal distribution) to estimate the average weight of a drug unit in the population, within a given confidence interval at a given confidence coefficient. This can be expressed as follows:

$$\overline{X} - \frac{S}{\sqrt{n}} t_{n-1,1-\tau/2} \leq \mu \leq \overline{X} + \frac{S}{\sqrt{n}} t_{n-1,1-\tau/2} \tag{7}$$

where

μ = the average weight of a drug unit in the population.
$\overline{X}$ = the average weight of a drug unit in the sample.
S = the standard deviation of $\overline{X}$.
n = sample size.
df = degrees of freedom (df = $n - 1$).
$t_{n-1,1-\tau/2}$ = the $1 - \tau/2$ percentile of the t distribution, with $n - 1$ degrees of freedom, obtained from an appropriate table.

Expression (7) applies to a sample taken from a very large population.

When the total population N is small so that n/N is greater than 0.1, a correction factor—the finite population correction factor $-\sqrt{(N-n)/N}$ should be used. Expression (7) becomes:

$$\bar{X} - \frac{S}{\sqrt{n}} t_{n-1,1-\tau/2} \sqrt{(N-n)/N} \leq \mu \leq \bar{X} + \frac{S}{\sqrt{n}} t_{n-1,1-\tau/2} \sqrt{(N-n)/N} \quad (8)$$

In calculating the total weight of the total drug exhibit, it is convenient to consider the point estimate $\hat{P}$ of the sample as representative of the parameter P of the population N.

The corresponding approximate confidence interval for the total weight of the drug exhibit W is then:

$$\hat{P}N\left\{\bar{X} - \frac{S}{\sqrt{n}} t_{n-1,1-\tau/2} \sqrt{(N-n)/N}\right\} \leq W \leq \hat{P}N\left\{\bar{X} + \frac{S}{\sqrt{n}} t_{n-1,1-\tau/2} \sqrt{(N-n)/N}\right\} \quad (9)$$

Summary of Criteria and Examples

Criteria were chosen so that for any number of nondrug units—r—anticipated in the initial sample, an appropriate predetermined sample size n will satisfy a confidence level $1 - \alpha$ that the proportion of drug units in the population is at least P_0 (see Tables 2 and 4 for several values of r, n and P_0).

These criteria are:

a) When no negatives are observed in the sample, or when the number of negatives observed in the initial sample is equal or less than that anticipated, then:

$$P_0 \geq 0.70$$
$$1 - \alpha \geq 90\%$$

b) When the number of negatives observed in the sample is greater than that anticipated in determining the initial sample size, then an additional sample is taken of a size sufficient to result in:

$$S_{\hat{p}} \approx 0.1$$

and in this situation we simply report the observed proportion of positives that is, P.

Our experience generally leads us to anticipate no negatives ($r = 0$) in the drug exhibit and to select the sample size accordingly. In cases where in fact no negatives are observed in the sample, the positive results provide the following quantities:

1. A point estimate $\hat{P} = 1$ with $S_{\hat{p}} = 0$ for the population parameter P.
2. A lower boundary estimate P_0, for P, at a confidence level $1 - \alpha$.

If some negative results which were not anticipated are observed in the initial sample the assumption $r = 0$ is not valid and a different sampling procedure is necessary. Various procedures are possible. Some fairly complicated ones are based on acceptance test theory [6–9]. Recently, a sequential sampling procedure based on demonstrating a given P_0 at a high confidence level has been suggested [5]. However, in the case of only a few observed negatives this procedure may require a very large sample size. Therefore, a simpler procedure, not concerned with the lower boundary P_0, is recommended here.

This procedure involves increasing the sample size until $S_{\hat{p}}$, the standard deviation of the point estimate $\hat{P}$ [Eq 5] becomes reasonably small (≈ 0.1). Some selected values of

the increased sample size and the point estimate which result in $S_{\hat{p}} \approx 0.1$ are presented in Table 5. In the event that a lower confidence boundary is of utmost importance, sampling can be continued until the sample size is ≥ 30 and then equation (6) can be used to obtain a reasonable approximation for the lower boundary.

Once sampling results are obtained, the confidence interval for the total weight W is calculated according to expression (9). The chosen confidence level is 95% ($\tau = 5\%$), hence, the t value in expression (9) is $t_{n-1,0.975}$.

The following case examples are given to illustrate and clarify the applications of this approach, using the criteria, equations and tables presented, for randomly selecting a sample size n sufficient for estimating the proportion P of drug units in the total drug exhibit and calculating its weight W.

Example—1

A seized drug exhibit contained 26 street doses (alleged drug units). According to the guidelines above (see also Table 3), a sample of 6 units was taken and each of them was analyzed and weighed. It was found that all 6 were drug units (heroin). Hence this sample size is sufficient to demonstrate that P_0 is at least 0.69 at a confidence level $1 - \alpha \geq 90\%$. The basis for the sample size of 6 is interpolation from Table 3. If it is desired to rigorously adhere to the criterion of $P_0 \geq 0.7$, the appropriate sample size is 7. The average net weight of the powder in the six units was 0.0425 g with a standard deviation of 0.0073 g.

What is the calculated weight W of the powder in the 26 doses?

Since the sample size is greater than 10% of the population size, the finite population correction factor should be used according to formula (8) and the confidence interval for μ will be:

$$0.0425 - (0.0073/\sqrt{6})t_{n-1,1-\tau/2}\,(26 - 6/26)^{0.5} \leq \mu \leq$$

$$0.0425 + (0.0073/\sqrt{6})t_{n-1,1-\tau/2}\,(26 - 6/26)^{0.5}$$

From t distribution tables for $n - 1 = 5$ degrees of freedom and for $\tau = 5\%$ (95% confidence level) the appropriate t value is $t_{5,0.957} = 2.57$. Substituting this value for $t_{n-1,1-\tau/2}$ and solving for μ one obtains:

$$0.0425 - 0.0067 \text{ g} \leq \mu \leq 0.0425 + 0.0067 \text{ g}$$

The point estimate from this sample is unity since all the sample units contained heroin. Substituting these values in expression (9) and solving for W:

$$1.11 - 0.17 \text{ g} \leq W \leq 1.11 + 0.17 \text{ g}$$

TABLE 5—*Sample size (n) as a function of population size (N) and the point estimate (P̂) maintaining a standard deviation of the point estimate* $S_{\hat{p}} \approx 0.10$.

	$\hat{P}$		
N	0.9	0.7	0.5
1 to 20	until 10	until 20	until 20
30	10	21	until 25
≥50	10	21	25

Example—2

Same as example 1, but one unit in the sample did not contain a drug. What is the minimum sample size that should be taken? Calculate the total weight of the drug in the exhibit.

Since we have one negative (in a small drug exhibit) we are not concerned with P_0, and the sample size is increased until $S_{\hat{p}} \approx 0.1$. If no additional negative results were found in the sample, then from Table 5 only four additional units should be taken, as a final sample of ten results in a proportion of 0.9 street doses containing heroin in the sample. The point estimate $\hat{P}$ for the proportion of drug units in the 26 street doses is 0.9. Assuming, for the sake of this example, that the additional sample size does not change the values of $\overline{X}$ and $S_{\hat{p}}$ from example 1, then:

$$1.00 - 0.15 \text{ g} \leq W \leq 1.00 + 0.15 \text{ g}$$

Conclusions

Using binomial and hypergeometric distribution functions, tables can be devised to determine sampling procedures with a sound and consistent statistical basis. By varying the basic parameters P_0, r, α, n and N, information can be generated to provide the basis for choosing a lower limit for the proportion of the population containing a drug at a desired confidence level. Sampling procedures can also be devised for determining the calculated weight of a population within given confidence limits using t distribution tables. The exact values to use in the tables may depend partially on legal precedents and local laws, but once these are established the appropriate tables may be used consistently.

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Address requests for reprints or additional information to
Mark Ravreby
Drug Analysis Unit
Division of Criminal Identification
National Police Headquarters
Jerusalem, Israel