

Facing an Extrapolation? Steps for Checking the Statistical Approach

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Agenda

- Review the various types of sampling used in compliance auditing, including a discussion of stratification.
- Address calculations behind extrapolation.
- Review the steps to take when your audit results are extrapolated to the population.
- Take-aways

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Purpose of Sampling

- The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandates that before using extrapolation to determine overpayment amounts, there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error.
- The purpose of sample is to use a portion of the population of interest to generalize back, or infer to, the population of interest.
- Saves time and money.

CMS Program Integrity Manual 8.4.1.2

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Defining Sample Sizes

- Probe: Determine whether problematic
 - OIG Self-Disclosure Protocol: 30
 - CMS: 20-40
- Full Sample
 - In a Corporate Integrity Agreement, the OIG required a Full Sample to be used, if the overpayment error rate, or financial error rate, in a probe sample is at or above 5%

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Major Steps in Statistical Sampling

- Select the provider or supplier
- Select the period to be reviewed
- Define the sampling universe, the sampling unit, and the sampling frame
- Design the sampling plan and select the sample
- Review each of the sampling units and determine any overpayments or underpayments
- Estimate the overpayment

CMS Program Integrity Manual 8.4.1.3

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Types of Samples

- Probability samples
 - The probability of selecting any one element from the population is known and equal.
- Non probability samples
 - The probability of selecting any one element from the population is not known and are not equal.



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Probability Sampling

- Regardless of the method of sample selection used, the Contractors shall follow a procedure that results in a probability sample. Two features must apply to be a probability sample:
 - It must be possible, in principle, to itemize a set of distinct samples in the target universe. Although only one sample will be selected, each distinct sample of the set has a known probability of selection.
 - Each sampling unit in each distinct possible sample must have a known probability of selection.

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Types of Probability Samples

- Simple random sampling
- Systematic sampling
- Stratified sampling
- Cluster Sampling

These methods should yield samples that have characteristics that are very close to those of the population

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Simple Random Sampling

Each member of the population has an equal and independent chance of being selected

- Steps to follow:
 - Define the population of interest
 - List all members of the population
 - Randomly select members from the population using some type of random process, e.g., computer program

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Simple Random Sampling Considerations

Use this method when the population members are similar to one another.

- Advantage:
 - Ensures a high degree of representativeness
- Disadvantage
 - Time consuming and tedious



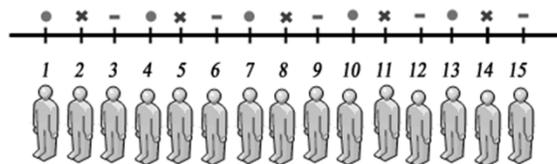
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Systematic Sampling

Here every n th item is selected

Steps to follow

- Make sure population is not sorted in any way
- Divide the population size by the desired sample size
- Choose a starting point at random
- Select every n th item from the starting point



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Systematic Sampling Considerations

- Use when the population members are similar to each other
- Advantage:
 - Ensures a high degree of representativeness
- Disadvantage:
 - Less random than simple random sampling because once the starting point is determined, each member does not have the same chance of being selected.

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Stratified Sampling

Used to assure that the strata in a population are fairly represented in the sample

- Especially important when the distinguishing factors (strata) are related to what is being studied
- Steps to follow
 - Members of each strata are listed separately
 - A random sample from each strata is selected

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Stratified Sampling Considerations

Used when the population is heterogeneous and contains different groups, some of which are related to the topic of the study.

- Advantages
 - Ensures a high degree of representativeness of all of the strata or layers in the population
- Disadvantage
 - Time consuming and tedious

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Cluster Sampling

Used when units of individuals are selected rather than the individuals themselves

- Steps to follow
 - Identify the units of interest
 - Randomly select a sample of the units
 - Examine each element within each selected unit

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Cluster Sampling Considerations

Use when the population consists of units rather than individuals

- Advantages
 - Easy and convenient
- Disadvantages
 - Members of units may be too different from each other

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Sample Validation

- Samples are validated by making sure that a characteristic of the sample, e.g., average payment per patient, is within a certain number of standard deviations of the population mean
 - Our methodology uses 1.96 standard deviations
- The validation demonstrates that the sample is a good representation of the population from which it was drawn

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Sampling Problems

- Sampling Error
- Bias



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Sampling Error

- Lack of fit between the sample and the population.
- The difference between the characteristics of the sample and the population from which the sample was selected and is a natural occurrence.
- The larger the sampling error, the less the sample results can be generalized to the population.

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Minimizing Sampling Error

- Increase the sample size as much as possible and reasonable
- Use probability sampling methods rather than non probability sampling methods
- At the extreme, conduct a census rather than perform sampling

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Biased Sample

A biased sample is one in which the method used to create the sample results in a sample that is systematically different from the population.

- Any generalization about the population made with a biased sample will not be valid.
- Solution is to use a randomly selected sample.

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Sample Size Considerations

- Confidence desired
- Level of variability in the population
- Precision level
 - Also know as effect size



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Confidence Level & Precision

Example:

Confidence Level = 95%

Precision = 7%

Sample Mean = \$50

Interpretation:

We can be 95% confident that the population mean will be between \$46.50 and \$53.50 (\$50 + or - 7%)

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When Will a Larger Sample Size Be Needed

A larger sample size will be needed when the amount of variability within groups is greater

- As elements become more diverse, a larger sample size will be needed to represent all of them.
- The difference between groups gets smaller
 - As the difference between groups gets smaller, a larger sample will be needed to reach the “critical mass” where the groups can differ.

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Final Sampling Issues

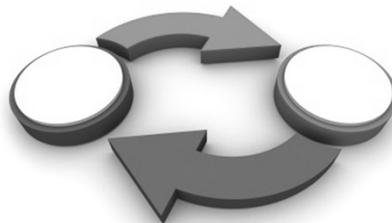
- Record (patient) substitution
- Projection of sample findings to the population



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Record Substitution

- Once a sample is selected, records (patients) can not be substituted.
 - Doing so invalidates the original sample and precludes the projection of findings back to the population



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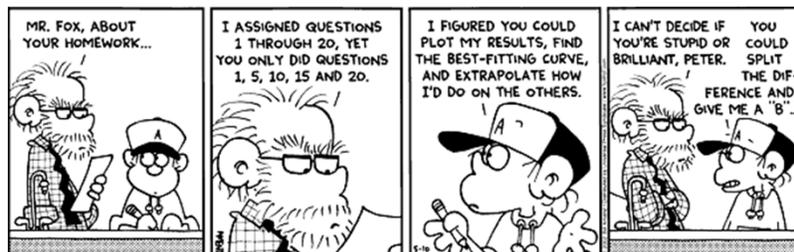
Types of Non Probability Samples

- Convenience sampling
 - Used when the units of interest are “captive”
- Quota sampling
 - Used when a stratified sample is desired, yet proportional stratification is not possible
 - Decide on strata definitions
 - Choose individuals in each strata until quota is reached

These methods will probably yield samples that have characteristics that are not close to those of the population

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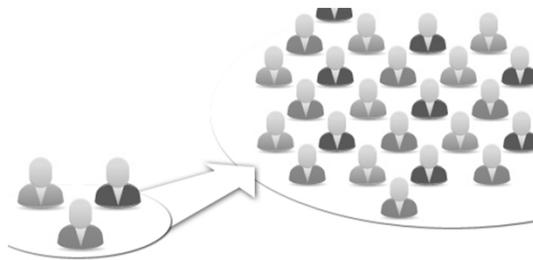
Extrapolation



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Extrapolation of sample findings

- Since a valid random sample is a representation , or a “mirror image” of the population, it is defensible to project sample findings onto the population from which the sample was drawn
 - This projection can include any characteristic of the sample



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Statistical Discussion



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Can OIG or others use Sampling and Extrapolation?

Determine overpayment in a manner that minimizes government's administrative burden.

- CMS Ruling 86-1.
 - Explains HCFA's authority to use statistical sampling to estimate overpayments made to physicians and suppliers. The ruling recognizes that statistical sampling conserves the resources of the Medicare program when reviews are performed on a large universe of claims.
- 42 U.S.C. § 1395gg(b) authorizes the Secretary to recoup from a provider or supplier "if more than the correct amount has been paid"
- 42 C.F.R. § 405.371 allows recoupment if a determination is made that a provider/supplier to whom payments are to be made has been overpaid.

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American Hospital Association

- November 20, 2014: AHA wrote the OIG regarding use of increased extrapolation; request to halt reviews and the demands to repay improperly extrapolated amounts.
 - Short inpatient stays
 - Not offsetting the amount of Part B payments with estimated overpayments
 - Using extrapolation without a clear process to challenge the OIG's sampling and extrapolation methodology through the claims appeal process
 - Misapplying or misinterpreting Medicare requirement

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American Hospital Association

- January 15, 2015 response:
 - OIG's application of a physician-order requirement is supported by legal authority; OIG consulted with CMS.
 - Medicare requires that a service must be reasonable and necessary to be payable. Admitting physician would expect the patient to stay 24 hours or more.
 - CMS is responsible for administering Medicare and contracts with MACs to process and pay claims. Providing an offset to the Part A overpayment with Part B reimbursement figures is not within the scope of these OIG reviews.
 - CMS allows for reopening of claims at any time provided that there is reliable evidence that the initial determination was procured by fraud or similar fault.
 - Use of statistical sampling in Medicare is well established and has repeatedly been upheld on administrative appeal within the Department and by Federal courts.

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When Results are Extrapolated

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Immediate Action

- Review the post audit report to determine identified issues.
- Take immediate action to correct the problems to prevent reoccurrence.
- Determine whether the regulations were properly interpreted.

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Extrapolated Results

- If possible, secure the services of a statistician to review the sample and extrapolation methodology
 - At least Masters Degree in Statistical Methods
 - Accredited by the American Statistical Association
 - Significant experience in the health care field
- Make sure to take advantage of all possible levels of audit appeal that are offered by the auditing entity in order to secure a fair and equitable settlement of the audit.

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Verification

- Statistician should determine if:
 - The sampling methodology employed by the auditing entity was truly random
 - The sampling methodology was appropriate
 - Attribute
 - Variable
 - The extrapolation methodology was appropriate and was only applied to audit findings that are subject to extrapolation.
 - Example: Medical necessity issues are sometimes not subject to being projected.

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Attorney/Consultant Involvement

- Attorney
 - Interpretation of specific policies of third party payers
 - Differing opinions of audit findings
 - Audit findings concerning federal, state, or local law
- Consultant
 - Work with the statistician to assist in recalculation of extrapolation
 - Assist in corrective actions and education
 - Assist in appeal process

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Discussion, Resources, and Checklist



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Questions

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