Sampling & Statistical Methods Utilized in Health Care Compliance

Frank Castronova, PhD, Pstat
Wayne State University

Andrea Merritt, ABD, CHC, CIA
Partner
Athena Compliance Partners

Agenda

- Review the various types of sampling used in compliance auditing, including a discussion of stratification.

- Discuss extrapolation

- Questions

Fraud, Waste, and Abuse

➤ CMS is now combating Fraud, Waste, and Abuse through nationally coordinated strategies.
  ➤ New data analytics
  ➤ Pattern recognition methods
  ➤ Analysis tools

➤ Extrapolation is not likely in automated reviews, but very likely in complex review, especially for inpatient claims or high dollar value claims.

Internal Efforts

- ➢ Increase internal auditing and monitoring efforts while integrating statistical expertise, when needed.
  - ➢ Valid samples are imperative.
  - ➢ If validity can be challenged, estimates and conclusions drawn for the universe are not sustainable.
- ➢ Ready to execute a response strategy in the case of a government audit
  - ➢ Add statistical expertise to a response team
    - ➢ Always verify government statistics and extrapolation is appropriate.

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

Why Sample?

- ➢ The characteristics of interest of the population are unknown
- ➢ Save time
- ➢ Save money

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Types of Samples

➢ Probability samples
  ➢ The probability of selecting any one element from the population is know 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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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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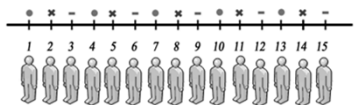
Systematic Sampling

Here every nth 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 nth 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

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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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Sampling Problems

- Sampling Error

- Bias

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Sampling Error

➤ Sampling error is the lack of fit between the sample and the population

➤ Sampling error is 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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Projection 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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Types of Non Probability Samples

• Convenience sampling

• Quota sampling

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

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Convenience Sampling

- Used when the units of interest are "captive"
- Steps to follow
  - Select the "captive" population
  - Select the sample

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Convenience Sampling Considerations

- Used when the members of the population are convenient to sample

- Advantages
  - Convenient and inexpensive

- Disadvantage
  - Results can not be generalized to the population

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Quota Sampling

- Used when a stratified sample is desired, yet proportional stratification is not possible

- Steps
  - Decide on strata definitions
  - Choose individuals in each strata until quota is reached

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Quota Sampling Considerations

➢ Use when strata are present and stratified sampling is not possible

➢ Advantages
  ➢ Insures some degree of representativeness of all the strata in the population

➢ Disadvantage
  ➢ Results can not be generalized to the population

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Definition of Data Mining

• Data mining is the process of sorting through large amounts of data and picking out relevant information. It is usually used by business intelligence organizations, and financial analysts, but is increasingly being used in the sciences to extract information from the enormous data sets generated by modern experimental and observational methods.

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Modeling

• Predictive modelling is the process by which a model is created or chosen to try to best predict the probability of an outcome. In many cases the model is chosen on the basis of detection theory to try to guess the probability of a signal given a set amount of input data, for example given a claim determining how likely that it is compliant.

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Predictive Modeling Methods

- Neural Networks
- Social Network Analysis
- Decision Trees
- Discriminant Analysis
- Logistic Regression

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Basic Inferential Statistical Methods

- Student t Test
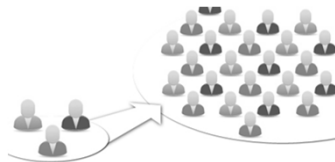- Analysis of Variance
- Chi-Square Analysis
- Regression Analysis

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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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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.

First Legal Case Finding Extrapolation Valid

- *Chaves County Home Health Service, Inc. v. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991), *cert. denied*, 402 U.S. 1091 (1992).
  - Statistical sampling does not violate due process "so long as extrapolation is made from a representative sample and is statistically significant."

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

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.

Recent – FCA Cases

- The AHA and Catholic Health Association urged the U.S. Court of Appeals to affirm a lower court ruling that relators seeking damages and penalties under the False Claims Act cannot use statistical sampling to prove a case challenging the exercise of medical judgment by a physician.

- DOJ's announcement on Oct. 24, 2016, that it reached a $145 million settlement agreement with Life Care Centers of America Inc. and its owner to resolve allegations of FCA violations for submitting false claims to Medicare and TRICARE.

Questions

Frank Castronova, PhD, Pstat

fcastronova@wowway.com

Andrea Merritt, ABD, CHC, CIA

Partner, Athena Compliance Partners

amerritt@athenacompliance.org