

# Scientific Evidence Code System

## Current Status of Code System Development (as of 8/22/2021)

|                               | Study Design | Statistic Type | Statistic Model | Risk of Bias | TOTAL |
|-------------------------------|--------------|----------------|-----------------|--------------|-------|
| #Expert Working Group Members | 70           | 66             | 64              | 64           | 75    |
| #Draft Terms                  | 56           | 110            | 98              | 257          | 588   |
| #Ontologies Identified        | 27           | 27             | 27              | 27           | 27    |
| #Terms Balloted               | 21           | NA             | 1               | 40           | 62    |
| #Terms Adopted                | 12           | NA             | NA              | 30           | 42    |

You are welcome to join this effort -- see [Invitation to join Expert Working Group](#).

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# Risk of Bias Code Systematic tem

## Introduction:

Precursor materials can be found in the [Risk of Bias](#) Code System Google Drive.

- 13 commonly used tools or systems were mapped for initial development of the Risk of Bias Code System.
- There were 257 draft terms in the [Risk of Bias and Safeguard Code System 2021 Feb 12](#). ([related image](#))

30 terms have been fully processed so far (with 100% agreement in voting by the Expert Working Group):

Parent concept:quality (BFO\_000019)

- **Bias (EBMO:00001)** = A systematic distortion in research results (estimation of effect, association, or inference)
  - **Selection Bias (EBMO:00002)**= A bias resulting from methods used to select subjects or data, factors that influence initial study participation, or differences between the study sample and the population of interest
    - **Participant Selection Bias (EBMO:00003)**= A selection bias resulting from methods used to select participating subjects, factors that influence initial study participation, or differences between the study participants and the population of interest.
      - **Inappropriate selection criteria (EBMO:00004)**= A selection bias resulting from inclusion and exclusion criteria used to select participating subjects that could result in differences between the study participants and the population of interest.
      - **Inappropriate sampling strategy (EBMO:00005)**= A selection bias resulting from the sampling frame, sampling procedure, or methods used to recruit participating subjects that could result in differences between the study participants and the population of interest.



include or exclude studies for evidence synthesis, or from differences between the study sample and the population of interest.

- **Confounding Covariate Bias (EBMO:00016)** = A situation in which the effect or association between an exposure and outcome is distorted by another variable. For confounding covariate bias to occur the distorting variable must be (1) associated with the exposure and the outcome, (2) not in the causal pathway between exposure and outcome, and (3) unequally distributed between the groups being compared.
  - **Allocation Bias (EBMO:00032)** = A confounding covariate bias resulting from methods for assignment of the independent variable by the investigator to evaluate a response or outcome.
    - **Inadequate allocation concealment (EBMO:00031)**= An allocation bias resulting from awareness of the assigned intervention before study enrolment and intervention assignment
  - **Comparator Selection Bias (EBMO:00033)**= A confounding covariate bias resulting from methods used to select participating subjects, or factors that influence participation, for the comparator group.
  - **Confounding difference (EBMO:00034)**= A confounding covariate bias in which the unequal distribution of a potentially distorting variable is recognized.
- **Performance Bias (EBMO:00017)**= A bias resulting from differences between the received exposure and the intended exposure.
  - **Inadequate blinding of participants (EBMO:00035)** = A performance bias due to awareness of the allocated intervention by participants.
  - **Inadequate blinding of intervention deliverers (EBMO:00036)** = A performance bias due to awareness of the allocated intervention by individuals providing or delivering the intervention.
  - **Deviation from study intervention protocol (EBMO:00037)**= A performance bias in which the intervention received differs from the intervention specified in the study protocol.
  - **Deviation from standard of care (EBMO:00038)**= A performance bias in which the intervention or exposure received differs from the usual practice or expected care.
  - **Nonadherence of implementation (EBMO:00039)**= A performance bias in which the intervention deliverers do not completely adhere to the expected intervention.
  - **Nonadherence of participants (EBMO:00040)**= A performance bias in which the participants do not completely adhere to the expected intervention or exposure.
  - **Imbalance in deviations from intended intervention (EBMO:00041)**= A performance bias in which the degree of

performance bias is unequally distributed between the groups being compared.

- **Attrition Bias (EBMO:00019)**= A bias due to absence of expected participation or data collection after selection for study inclusion.
- **Analysis Bias (EBMO:00021)**= A bias related to the analytic process applied to the data.
  - **Bias related to selection of analysis (EBMO:00022)** (Analysis Selection Bias) = An analysis bias due to inappropriate choice of analysis methods before the analysis is applied.

### **The following 14 terms are out for vote by the Risk of Bias Code System Development Expert Working Group:**

•**Detection Bias (EBMO:00020) [Draft Term]**= A bias due to distortions in how variable values (data) are determined. {Comment for application: Determination may include ascertainment or assessment (classification or measurement).}

•**Outcome Detection Bias (EBMO:00042) [Draft Term]**= A detection bias due to distortions in how an outcome is determined.

•**Cognitive Interpretive Bias for outcome determination (EBMO:00047) [Draft Term]**= An outcome detection bias due to the subjective nature of human interpretation.

- **Observer bias for outcome determination (EBMO:00049) [Draft Term]**= A cognitive interpretive bias for outcome determination due to subjective interpretations in the process of observing and recording information.
- **Recall bias for outcome determination (EBMO:00050) [Draft Term]**= A cognitive interpretive bias for outcome determination due to differences in accuracy or completeness of recall of past events or experiences.
- **Apprehension bias for outcome determination (EBMO:00051) [Draft Term] (Hawthorne effect for outcome determination)** = A cognitive interpretive

bias for outcome determination due to study participants' awareness of being observed resulting in different responses or behaviors.

- **Lack of blinding for outcome determination (EBMO:00048) [Draft Term] (Lack of blinding during outcome assessment)** = A cognitive interpretive bias for outcome determination due to the outcome assessor's awareness of the participant's status with respect to the exposure of interest.

- **Outcome Ascertainment Bias (EBMO:00058) [Draft Term] (Ascertainment bias for outcome determination)** = An outcome detection bias due to distortions in how the data are collected.

- **Outcome Measurement Bias (EBMO:00059) [Draft Term] (Measurement bias for outcome determination)** = An outcome detection bias due to distortions in how the data are measured.

- **Outcome Misclassification Bias (EBMO:00060) [Draft Term] (Misclassification bias for outcome determination)** = An outcome detection bias due to distortions in how the data are classified.

- **Exposure Detection Bias (EBMO:00043) [Draft Term]** = A detection bias due to distortions in how an exposure of interest is determined. {Comment for application: The exposure of interest can be an intervention or a prognostic factor, depending on the research context.}

- [child terms will be derived following the model developed for Outcome Detection Bias]

- **Confounder Detection Bias (EBMO:00044) [Draft Term]** = A detection bias due to distortions in how the data for a potential confounder are determined.

- [child terms will be derived following the model developed for Outcome Detection Bias]

- **Detection Bias related to the Reference Standard (EBMO:00045) [Draft Term] (Bias for reference standard result determination)** = A detection bias due to distortions in how the reference standard result is determined.

- [child terms will be derived following the model developed for Outcome Detection Bias]

•**Detection Bias related to the Index test (EBMO:00046)[Draft Term] (Bias for index text result determination)** = A detection bias due to distortions in how the index text result is determined.

•[child terms will be derived following the model developed for Outcome Detection Bias]

The following terms are in development for vote by the Risk of Bias Code System Development Expert Working Group:

- **Diagnostic suspicion bias for outcome determination = A cognitive interpretive bias for outcome determination in which knowledge of a subject's prior exposures or personal biases may influence both the process and the outcome of diagnostic tests.**
- **Hypothetical bias for outcome determination = A cognitive interpretive bias for outcome determination in which a distortion that arises when an individual's stated behavior or valuation differs to that of their real behavior or valuation.**
- **Mimicry bias for outcome determination = A cognitive interpretive bias for outcome determination in which an innocent exposure may become suspicious if, rather than causing disease, it causes a benign disorder which resembles the disease.**
- **Previous opinion bias for outcome determination = A cognitive interpretive bias for outcome determination in which the results of a previous assessment, test result or diagnosis, if known, may affect the results of subsequent processes on the same participant.**
- **Perception bias for outcome determination = A cognitive interpretive bias for outcome determination in which the researcher's or participant's tendency to be subjective about people and events causes biased information to be collected in a study or biased interpretation of a study's results.**
- **Unacceptability bias for outcome determination (Unacceptable disease bias for outcome determination) = A cognitive interpretive bias for outcome determination in which a participant's assessment of "unacceptability" of an outcome results in systematic**

differences in response values, response rates or uptake of tests.

- **Outcome Classification System Bias (Definition bias for outcome determination, Outcome definition bias) = An outcome misclassification bias related to ...**
- **Outcome Classification Process Bias (Classification process bias for outcome determination) = An outcome misclassification bias related to ...**
- **Incorporation Bias for outcome determination = An outcome misclassification bias in which ...**

If you want to vote on these definitions you can join the Expert Working Group -- see [Invitation to join Expert Working Group](#).

## [Study Design Code System](#)

Introduction:

Precursor materials can be found in the [Study Design Code System Google Drive](#).

- 6 commonly used tools or systems mapped for initial development of the Study Design Code System.
- There are now 56 draft terms in the [simplified Study Design Code System concept list](#)

12 terms have been fully processed so far (with 100% agreement in voting by the Expert Working Group):

- **Study Design = A plan specification for how and what kinds of data will be gathered as part of an investigation which may produce testable explanations, conclusions and predictions or test a hypothesis.**

- **Interventional Research = A study design in which an independent variable (an exposure or intervention) is prospectively assigned or modified by the investigator to evaluate a response in the dependent variable (an effect or outcome).**
  - **Randomized assignment (Interventional research with randomized assignment, Randomized trial, Randomized controlled trial, RCT, Randomization, Random allocation) = An interventional study design in which an independent variable (an exposure or intervention) is prospectively assigned or modified by random chance to separate groups.**
    - **Simple randomization = A randomized assignment in which each participant has the same prespecified likelihood of being assigned to a group as all other participants, independent of the assignment of any other participant.**
    - **Stratified randomization = A randomized assignment in which participants are stratified into groups based on prognostic variables and then randomized into balanced treatment groups.**
    - **Block randomization = A randomized assignment in which a pre-specified number of subjects is assigned to a block containing the same pre-specified ratio of group assignments in random order.**
    - **Adaptive randomization = A randomized assignment in which a participant's groups assignment probability is adjusted based on any factor such that the likelihood of assignment is not the same for all participants.**
  - **Non-randomized assignment = An interventional study design in which an independent variable (an exposure or intervention) is prospectively assigned or modified by methods other than random chance to separate groups.**
    - **Quasi-randomized assignment = An interventional study design with a method of allocation that is not limited to random chance but is intended to produce similar baseline groups for experimentation. {Quasi-random methods of allocation include allocation by alternate order of entry, date of birth, day of the week, month of the year, or medical record number}**
- **Observational Research = A study design in which the independent variables (exposures or interventions) are not prospectively assigned or modified by the investigator.**
- **Comparative study design (Comparative research) = A study design in which two or more groups are compared.**
  - **Parallel cohort design (Concurrent cohort study) = A comparative study design in which the groups are compared concurrently and participants are expected to remain in the groups being compared for the entire duration of participation in the study.**

**The following 9 terms are out for vote by the Study Design Code System Development Expert Working Group:**

- **Comparative study design (Comparative research) = A study design in which two or more groups are compared.**
  - **Crossover cohort design (Crossover study, Crossover trial) = A comparative study design in which participants receive two or more alternative exposures during separate periods of time.**
    - **Controlled crossover cohort design = A crossover cohort design in which two or more cohorts have different orders of exposures.**
    - **Single-arm crossover design = A crossover cohort design in which all participants are in a single cohort with the same order of exposures.**
  - **Case control design = A comparative study design in which the groups being compared are defined by outcome presence (case) or absence (control).**
  - **Matching for comparison (Matched study design) = A comparative study design in which individual participants in different groups being compared are paired or matched into sets based on selected attributes for within-set analysis.**
  - **Cluster as a unit of allocation (Clustering for comparison) = A comparative study design in which participants are allocated to exposures (interventions) by their membership in groups (called clusters) rather than by individualized assignments.**
- **Non-comparative study design (Non-comparative research, Descriptive study) = A study design with no comparisons between groups with different exposures and no comparisons between groups with different outcomes.**
  - **Uncontrolled cohort design (Single cohort design, Case series design, Non-controlled cohort design) = A non-comparative study design in which two or more participants are evaluated in a single group (or cohort).**
  - **Case report (Case study) = A non-comparative study design in which a single participant is evaluated.**

**The next set of terms to be drafted include:**

- **Comparative study design (Comparative Research) = A study design in which two or more groups are compared.**
  - **Time series design (Multiple time point comparison) = A comparative study design in which ...**
    - **Before-After comparison = A time series design in which ...**
  - **Family study design = A comparative study design in which ...**
    - **Twin study design = A family study design in which ...**
  - **Ecological design (Population-based design) = A comparative study design in which ...**

If you want to vote on these definitions you can join the Expert Working Group -- see [Invitation to join Expert Working Group](#).

## Statistic Model Code System

The context of application of these Statistic Model Codes will be:

### Structure

| Name                | Flags      | Card. | Type  | Description & Constraints  |
|---------------------|------------|-------|---|--|
| Statistic           | Σ <b>D</b> |       | Element   | Single statistic<br>Elements defined in Ancestors: <i>id</i> , <i>extension</i> , <i>modifierExtension</i> |
| description         | Σ          | 0..1  | string  | Description of content   |
| note                | Σ          | 0..*  | Annotation  | Footnotes and/or explanatory notes   |
| statisticType       | Σ          | 0..1  | CodeableConcept                                   | Type of statistic, eg relative risk<br><i>StatisticType</i> (Extensible)                                   |
| quantity            | Σ          | 0..1  | Quantity  | Statistic value  |
| numberOfEvents      | Σ          | 0..1  | unsignedInt                                       | The number of events associated with the statistic   |
| sampleSize          | Σ          | 0..1  | Element   | Number of samples in the statistic   |
| attributeEstimate   | Σ          | 0..*  | Element   | An attribute of the Statistic  |
| modelCharacteristic | Σ          | 0..*  | Element   | Model characteristic   |
| code                | Σ          | 1..1  | CodeableConcept                                   | Model specification<br><i>StatisticModelCode</i> (Extensible)  |
| value               | Σ          | 0..1  | SimpleQuantity                                    | Numerical value to complete model specification  |
| variable            | Σ          | 0..*  | Element   | A variable adjusted for in the adjusted analysis   |
| variableDefinition  | Σ          | 1..1  | Reference(Group<br> <br>EvidenceVariable)<br>code | Description of the variable  |
| handling            | Σ          | 0..1  | code  | continuous   dichotomous   ordinal   polychotomous<br><i>EvidenceVariableHandling</i> (Required)           |
| valueCategory       | Σ          | 0..*  | CodeableConcept                                   | Description for grouping of ordinal or polychotomous variables   |
| valueQuantity       | Σ          | 0..*  | Quantity  | Discrete value for grouping of ordinal or polychotomous variables  |
| valueRange          | Σ          | 0..*  | Range   | Range of values for grouping of ordinal or polychotomous variables   |

The **Statistic Standard and Terminology Working Group** discussed the overall framework for coordinating the Statistic Model Code System with the STATO Statistics Ontology.

We determined the term “statistical model” can be reclassified as an “information content entity” in STATO and we can then map out statistical model terms similar to what we did for “statistic” terms for our Statistic Type Code System.

However, we also determined that some of the terms we want to include in our Statistic Model Code System (to support expression in Evidence.statistic.modelCharacteristic.code elements) are technically not statistical models. These terms are likely statistical processes and be found in the “statistical hypothesis test” class within STATO. For these terms we will map terms following the current outline in STATO and see how well it fits our functional application.

Information content entity

- Hypothesis test attribute
  - alpha setting
    - alpha setting with subtype unspecified
    - individual test alpha without multiple testing adjustment
    - overall alpha with multiple testing
    - individual test alpha with multiple testing adjustment
  - one-tailed test (one threshold)
  - two-tailed test (two thresholds)
- Statistical model characteristic
  - Covariate term [10]
  - Interaction term
  - Fixed-effect model (common-effect model, one true effect size)
  - Random-effects model (random effects, true effect sizes are distributed)
  - Generalized Linear Mixed Model (GLMM)
    - GLMM with probit link
    - GLMM with logit link
    - GLMM with identity link
    - GLMM with log link
    - GLMM with generalized logit link
    - GLMM with subtype unspecified [20]
  - GLM (Generalized Linear Model)
    - GLM with probit link
    - GLM with logit link (Logistic Regression)
    - GLM with identity link (Linear Regression)
    - GLM with log link
    - GLM with generalized logit link
    - GLM with subtype unspecified
  - Regression Model Form
    - Linear Regression (GLM with identity link)
    - Logistic Regression (GLM with logit link) [30]

- Log Linear Regression
- Polynomial Regression
- Cox Proportional Hazards
- o Regression Model Distribution
  - Normal Distribution for Regression
  - Log Normal Distribution for Regression
  - Exponential Family of Distributions for Regression
  - Binomial Distribution for Regression (Binomial Regression)
  - Multinomial Distribution for Regression (Multinomial Regression)
  - Poisson Regression (Poisson Distribution for Regression) [40]
  - Negative Binomial Regression (Negative Binomial Distribution for Regression)
- o Statistical model goal
  - Adjustment for clustering
  - Adjustment for covariates [44]

process

- Data transformation
  - o Data imputation
    - Zero-cell adjustment with constant
    - Zero-cell adjustment with continuity correction
  - o Meta-analysis
    - Meta-analysis with fixed-effect model
      - Meta-analysis using inverse variance method
      - Meta-analysis using Mantel-Haenszel method [50]
      - Meta-analysis using Peto method
    - Meta-analysis with random-effects model
      - Meta-analysis using Dersimonian-Laird method (correct the spelling for: meta analysis by DerSimonian and Leard method)
      - Meta-analysis using Paule-Mandel method
      - Meta-analysis using Restricted Maximum Likelihood method
      - Meta-analysis using Maximum Likelihood method
      - Meta-analysis using Empirical Bayes method
      - Meta-analysis using Hunter-Schmidt method (meta analysis by Hunter-Schmidt method)
      - Meta-analysis using Hartung-Knapp-Sidik-Jonkman method (may need to add synonyms of HKSJ method, Hartung-Knapp method, Sidik-Jonkman method)
      - Meta-analysis using modified Knapp-Hartung method (may have synonym of mKH method, modified Hartung-Knapp method) [60]
      - Meta-analysis using Hedges method [61]
- o Statistical hypothesis test
  - Between group comparison statistical test
    - ANOVA
      - o multivariate ANOVA (MANOVA)
      - o Multiway ANOVA
        - ?? 3-way ANOVA
      - o One-way ANOVA

- o Repeated measure ANOVA
- o Two-way ANOVA [70]
  - ?? 2-way ANOVA without replication
  - ?? 2-way ANOVA with replication
- Non-parametric test
  - o Kruskal Wallis test
  - o Log rank test
  - o Mann-Whitney U-test (?? Wilcoxon Rank-Sum test; U test; Wilcoxon rank-sum test; rank-sum test for the comparison of two samples)
  - o McNemar test ((move from information content entity))
  - o Sign test
  - o Friedman test
- Two sample t-test (2-sample t-test, independent) [80]
  - o Two sample t-test with equal variance
  - o Two sample t-test with unequal variance
- Z test for between group comparison
- Chi square test
  - Chi square test for homogeneity
  - Mantel-Haenszel method (Cochran-Mantel-Haenszel Chi-Squared Test for Count Data)
  - Pearson's Chi square test of goodness of fit
  - Pearson's Chi square test of goodness of independence between categorical variables
    - o Yate's corrected Chi-Squared test
- Single-sample reference comparison statistical test [90]
  - One sample t-test (1-sample t-test)
  - Z test for single-sample
- Test of association between categorical variables
  - Cochran-Armitage test for trend
  - Fisher's exact test
- Within subject comparison statistical test
  - Paired t-test (2-sample t-test, dependent, matched pair t-test)
  - Wilcoxon signed rank test [98]

## Statistic Type Code System

§This list has 110 non-redundant codable concepts for the **Statistic Type Code System**:

statistic = An information content entity that is a formalization of relationships between variables and value specification. ((The "statistic" does not include the inference for which the statistic is

used—that would be found in the variable specification, and does not include the model characteristics.))

1. Count
2. Sum
3. Maximum Observed Value
4. Minimum Observed Value
5. Ancillary Statistic
  - a. Maximum Possible Value
  - b. Minimum Possible Value
  - c. Cutoff value
  - d. Degrees of Freedom
6. Measure of Central Tendency
  - a. Mean (Arithmetic Mean, Average)
  - b. Geometric Mean
  - c. Median
  - d. Mode
7. Difference
  - a. Count Difference
  - b. Mean Difference
  - c. Standardized Mean Difference
    - i. Cohen's d statistic
    - ii. Strictly standardized mean difference
    - iii. Hedges's g
    - iv. Glass's delta
  - d. Median Difference
  - e. Risk Difference
  - f. Relative Risk Difference
8. Reciprocal of Difference
  - a. Number Needed to Treat (NNT, Number needed to treat to benefit, NNTB)
  - b. Number Needed to Screen (NNS)
  - c. Number Needed to Diagnose (NND)
  - d. Number Needed to Harm (NNH, Number needed to treat to harm, NNTH)
9. Ratio
  - a. Percentage
  - b. Proportion
    - i. Incidence (Cumulative Incidence, Incidence Proportion) (Conditional Risk)
    - ii. Prevalence (Period Prevalence, Point Prevalence, Lifetime Prevalence)
    - iii. Sensitivity
    - iv. Specificity
    - v. Positive Predictive Value
    - vi. Negative Predictive Value
  - c. Odds
  - d. Rate
    - i. Incidence Rate (Incidence Density) (Average Hazard Rate)
    - ii. Hazard Rate (Hazard, Hazard Function, Instantaneous Hazard Rate)
  - e. Ratio-based Measure of Association

- i. Hazard Ratio
- ii. Incidence Rate Ratio (IRR)
  - 1. Standardized Incidence Ratio (SIR)
- iii. Odds Ratio
- iv. Prevalence Ratio
- v. Risk Ratio (Relative Risk)
- vi. Likelihood Ratio Positive
- vii. Likelihood Ratio Negative
- viii. Positive Clinical Utility Index
- ix. Negative Clinical Utility Index
- x. Ratio-based Measure of Agreement
  - 1. Diagnostic Accuracy
  - 2. Diagnostic Odds Ratio
  - 3. Kappa
    - a. Bennett's Kappa
    - b. Cohen's Kappa
    - c. Scott's Kappa
  - 4. Misclassification Rate
  - 5. F1-score

#### 10. Measure of Correlation

- a. Covariance
- b. Pearson Correlation Coefficient
- c. Regression Coefficient
- d. Spearman Rank-Order Correlation Coefficient
- e. Matthews Correlation Coefficient
- f. Kendall Correlation Coefficient
- g. Goodman and Kruskal's Gamma
- h. Calibration
  - i. Mean calibration
  - ii. Calibration-in-the-large
  - iii. Calibration intercept
  - iv. Calibration slope

#### 11. Measure of Dispersion

- a. Range
- b. Interquartile range
- c. Standard deviation
  - i. Standard deviation for population
  - ii. Standard deviation for sample
  - iii. Sampling standard deviation
- d. Variance
  - i. Variance for population
  - ii. Variance for sample
  - iii. Sampling variance
- e. Gini index
- f. Measure of Dispersion of Statistic
  - i. Standard error
    - 1. Standard error of the mean
    - 2. Standard error of the median

3. Standard error of the proportion
    4. Standard error of the difference between means
    5. Standard error of the difference between proportions
  - ii. Credible interval
  - iii. Confidence interval
12. Measure of Discrimination
  - a. Area Under the Curve (AUC)
    - i. C-statistic
13. Measure of Heterogeneity
  - a. Chi square for homogeneity
  - b. Cochran's Q statistic (Chi squared for heterogeneity)
  - c. I-squared
  - d. Tau squared
14. Hypothesis Testing Measure
  - a. Chi square for independence
  - b. Chi square for trend
  - c. P-value
  - d. Z-score
  - e. T-score
15. Modifier Code
  - a. Predicted Data Item – add to any other Statistic Type code to note predicted form (not observed form) of that statistic type

**Note:**

Terms that we would like to come back to later:

Hotelling T<sup>2</sup>-model characteristic