COVID-19 Knowledge Accelerator (COKA) Risk of Bias Terminology and Tooling Working Group Progress Report

If you wish to sign up or learn more about COKA please go to https://www.gps.health/covid19_knowledge_accelerator.html. Additional resources for finding the COVID-19 evidence (research collections and research registries) can be found at https://covid-19.ebscomedical.com/

For the Risk of Bias Code System Development Steering Group – work group folder, progress notes

To participate in any of the working groups you can use this link to join the microsoft meeting.

Below is the overall list of groups and weekly meeting schedule.

The Risk of Bias Code System Terminology and Tooling Working Group meets Fridays at 9-10 am Eastern.

*This group was previously called the Risk of Bias Code System Development Steering Group

Join Microsoft Teams Meeting

+1 929-346-7156 United States, New York City (Toll)
Conference ID: 324 918 025#
Local numbers
Meeting support by ComputablePublishing.com

Prior to September 11, 2020 this group was called the COKA Quality/Certainty Rating Process Development Work Group. The broad focus of the group is to develop and maintain processes for expression of assessments of quality or certainty regarding evidence at both the level of study results and bodies of evidence.

Starting September 11, 2020 this group became the Risk Of Bias Code System Development Steering Group.

- Meeting time: **Fridays** at 9:00am to 10:00am ET
- Starting 10/19/2020 Attendance and contact information for participants can be found here.

If you wish to sign up please go to https://www.gps.health/covid19_knowledge_accelerator.html

Progress reports

January 28, 2022

We discussed the use of “participants” to describe the entity being observed in a research study. Although other terms could be used we think that this is the most respectful and overarching term to describe a wide variety of situations. The following blog was shared in the meeting to add to the conversation. The blog describes a study that

asked patients what they would like to be called and "participant" was the preferred choice. https://blog.primr.org/subjects-vs-participants/

a reference listed in the blog is here: https://www.ncbi.nlm.nih.gov/pubmed/25790380

January 21,2022

https://www.semanticscholar.org/paper/Guidelines-for-writing-definitions-in-ontologies-Sepp%C3%A4l%C3%A4-Ruttenberg/ba6883c40153a41ecf61d5c56d3b12706e7f4026

Pearls of wisdom to follow when building or using an ontology

1) The ontology is not a rating system but rather provides language for a rating system including type, level and direction of bias.

2)We need to revisit the definitions and include SEVCO numbers for all referenced terms.

3) Graphics need to be included (Harold has been building diagrams to represent many concepts)

4) As we do this we are learning how to write the definitions and would do things differently if we started again. Therefore , early definitions may need to be revisited.

5) We have made assumptions that may or may not be consistent or correct

November 26, 2021

Meeting canceled in observance of Thanksgiving Holiday.

November 19, 2021

The group concentrated on the software for voting and a discussion about attribution for voting members of the expert working group.

Quote for the day:"The challenge with creating a new reality is you have to invent every part of it." –stated in the COKA Risk of Bias Terminology and Tooling Working Group

November 12, 2021

The risk of bias group reviewed recent changes to the code system builder including the ability to comment.

No one gets a notification at this time when a comment is added but there is a follow button that will be activated in the future.

The voting function is a higher priority for development .

Being a member of the expert working group will allow member ship in a group that gives you permission to vote in the form of a yes/no comment

We need to work out how voting will function

We reviewed previous votes and decisions regarding outcome detection bias terms.

It was suggested that we add a property-response to comment on the code system and fill in our responses to comments from the EWG.

We will need to re-write our protocol to fit our new workflow once we have developed it.

The rest of the time was used to map the logic involved.

Recognize whether a term is eligible for voting

In term detail for specific term

-is term eligible for vote?

Display “open for voting”

Type string not Boolean

Consider using a date range when it is open for vote

If eligible= true or is left blank

If true consider highlighting in yellow

Check if term is open for voting

Present button to user,

If clicked,

Check if user ID is member of group

If yes continue, if no ask to join and develop a way to add to EWG

November 5, 2021

Sevco:102 was removed (deprecated) from the code system -in the future we will code that something is missing instead of including a term for missing or unclear for each concept.

Oct 29, 2021

The Risk of Bias Terminology and Tooling Working Group reviewed the ballot results for 3 terms (types of Outcome Ascertainment Bias). Two terms passed, and the comments on one term led to the addition of a "Comment for application". The current set of these terms is now:

- **Outcome Ascertainment Bias (SEVCO:00058) (Ascertainment bias for outcome determination) = An outcome detection bias due to distortions in how the data are collected.**
  - **Nonrepresentative observation period for outcome of interest (SEVCO:00097) (Misaligned follow up period for outcome of interest) = An outcome ascertainment bias due to differences in the period used for observation of the outcome and the period for the outcome of interest.**
  - **Undependable method for outcome ascertainment (SEVCO:00098) (Error in data collection not minimized for outcome determination) [Draft Term] = An outcome ascertainment bias due to methods of data collection that result in inconsistent or incorrect data values. {Comment for application: This term is used when the method used for outcome ascertainment is incorrect, insensitive, or nonspecific. If the method (whether dependable or undependable) is applied inconsistently, then use the term "Inconsistency in application of outcome ascertainment".}**
  - **Inconsistency in application of outcome ascertainment (SEVCO:00099) (Imbalance in application of outcome ascertainment) = An outcome ascertainment bias due to differences within or between groups in how the data are collected.**

You can also view these terms at the following links:

- **https://fevir.net/resources/CodeSystem/27270#SEVCO:00097**
- **https://fevir.net/resources/CodeSystem/27270#SEVCO:00098**
- **https://fevir.net/resources/CodeSystem/27270#SEVCO:00099**
- **the Scientific Evidence Code System (https://gps.health/scientific-evidence-code-system/)**

For one of the terms (Inconsistency in application of outcome ascertainment) a comment led us to create a new term property ("Proposed Change for Future Vote") and we set the value of this property to: Add alternative terms "Variation in application of outcome ascertainment" and "Inconsistency in application of method of outcome ascertainment"

This will help us develop methods for future changes to terms after initial approval. We will ultimately develop a system for continuous updating of the code system.

We will send 6 terms (types of Outcome Measurement Bias) for the next ballot for review by the Risk of Bias Code System Expert Working Group:

- **Outcome Measurement Bias (SEVCO:00059) (Measurement bias for outcome determination) = An outcome detection bias due to distortions in how the data are measured.**
    - **Inappropriate outcome measurement method (SEVCO:00100) (Incorrect outcome measurement method) [Draft Term] = An outcome measurement bias due to use of an incorrect method or protocol.**
    - **Insensitive measure bias for outcome determination (SEVCO:00101) (Inadequate sensitivity for outcome measure) [Draft Term] = An outcome measurement bias due to use of a method that does not reliably detect the outcome when the outcome is present. (Comment for application: Use of an inadequately sensitive outcome measure is likely to result in false negative findings.)**
    - **Nonspecific measure bias for outcome determination (SEVCO:00211) (Inadequate specificity for outcome measure) [Draft Term] = An outcome measurement bias due to use of a method that falsely detects the outcome when the outcome is absent. (Comment for application: Use of an inadequately specific outcome measure is likely to result in false positive findings.)**
    - **Unclear outcome measurement method (SEVCO:00102) [Draft Term] = An outcome measurement bias due to use of a method that is not reported with sufficient clarity and detail such that measurement could be replicated.**
    - **Inappropriate outcome measurement conduct (SEVCO:00103) [Draft Term] = An outcome measurement bias due to incorrect application of the method or protocol.**
    - **Inconsistency in application of outcome measurement (SEVCO:00104) (Imbalance in application of outcome measurement) [Draft Term] = An outcome measurement bias due to differences within or between groups in how the data are measured.**

October 15. 2021

Changes were made to the following terms:

- **Outcome Ascertainment Bias (SEVCO:00058)** (Ascertainment bias for outcome determination) = An outcome detection bias due to distortions in how the data are collected.
    - **Misaligned ~~Inappropriate~~ follow up period for outcome of interest (SEVCO:00097) [Draft Term]** = An outcome ascertainment bias due to differences in the time period used for observation of the outcome and the true time period for outcome occurrence.
    - **Undepend~~reli~~able method for outcome ascertainment (SEVCO:00098)** (Error in data collection not minimized for outcome determination) **[Draft Term]** = An outcome ascertainment bias due to methods of data collection that result in inconsistent or incorrect data values.

The Risk of Bias Terminology and Tooling Working Group reviewed feedback and revised (additions in green, deletions in red) 2 of the 13 terms recently voted on by the Risk of Bias Code System Expert Working Group:

- **Bias (SEVCO:00001) (False Certainty) = A systematic distortion in research results (estimation of effect, association, or inference). Distortions in research results means differences between the reported results**

(findings, conclusions, effect estimates) and the actuality (the truth, the estimand [the quantity targeted for estimation]).

- Detection Bias (SEVCO:00020) = 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 (SEVCO:00042) = A detection bias due to distortions in how an outcome is determined.
- Outcome Ascertainment Bias (SEVCO:00058) (Ascertainment bias for outcome determination) = An outcome detection bias due to distortions in how the data are collected.
    - Misaligned Inappropriate follow up period for outcome of interest (SEVCO:00097) [Draft Term] = An outcome ascertainment bias due to differences in the time period used for observation of the outcome and the true time period for outcome occurrence.
    - Undependable Unreliable method for outcome ascertainment (SEVCO:00098) (Error in data collection not minimized for outcome determination) [Draft Term] = An outcome ascertainment bias due to methods of data collection that result in inconsistent or incorrect data values.
    - Imbalance in application of outcome ascertainment (SEVCO:00099) [Draft Term] = An outcome ascertainment bias due to differences within or between groups in how the data are collected.
- Outcome Measurement Bias (SEVCO:00059) (Measurement bias for outcome determination) = An outcome detection bias due to distortions in how the data are measured.
    - Outcome measurement method inappropriate (SEVCO:00100) [Draft Term] = An outcome measurement bias due to use of an incorrect method or protocol.
    - Insensitive measure bias for outcome determination (SEVCO:00101) (Inadequate sensitivity for outcome measure) [Draft Term] = An outcome measurement bias due to use of a method that does not reliably detect the outcome when the outcome is present. (Comment for application: Use of an inadequately sensitive outcome measure is likely to result in false negative findings.)
    - Nonspecific measure bias for outcome determination (SEVCO:00211) (Inadequate specificity for outcome measure) [Draft Term] = An outcome measurement bias due to use of a method that falsely detects the outcome when the outcome is absent. (Comment for application: Use of an inadequately specific outcome measure is likely to result in false positive findings.)
    - Outcome measurement method unclear (SEVCO:00102) [Draft Term] = An outcome measurement bias due to use of a method that is not reported with sufficient clarity and detail such that measurement could be replicated.
    - Outcome measurement conduct inappropriate (SEVCO:00103) [Draft Term] = An outcome measurement bias due to incorrect application of the method or protocol.
    - Imbalance in application of outcome measurement (SEVCO:00104) [Draft Term] = An outcome measurement bias due to differences within or between groups in how the data are measured.
- Outcome Classification Bias (SEVCO:00060) (Misclassification bias for outcome determination, Outcome Misclassification Bias) = An outcome detection bias due to distortions in how the data are classified.
    - Outcome Classification System Bias (SEVCO:00061) (Definition bias for outcome determination, Outcome definition bias) = An outcome classification bias resulting from the definition or threshold used for outcome classification.
        - Nonrepresentative definition for outcome classification (SEVCO:00105) [Draft Term] = An outcome classification system bias due to a definition or threshold that does not represent the outcome of interest.
            - Surrogate marker bias for outcome classification (SEVCO:00108) [Draft Term] (Substitution bias for outcome classification) = A nonrepresentative definition for outcome classification due to use of a factor associated with the outcome rather than a direct observation of the outcome.
        - Definition not prespecified for outcome classification (SEVCO:00106) [Draft Term] = An outcome classification system bias due to absence of a predetermined definition.
        - Definition unclear for outcome classification (SEVCO:00107) [Draft Term] = An outcome classification system bias due to use of a definition that is not reported with sufficient clarity and detail such that classification could be replicated.

- **Outcome Classification Process Bias (SEVCO:00062) (Classification process bias for outcome determination) = An outcome classification bias resulting from the application of the method used for outcome classification.**
- **Incorporation Bias for outcome determination (SEVCO:00063) = An outcome classification bias due to the inclusion of the exposure under investigation in the method or process used for outcome classification.**

We will continue discussions of these terms (and how to resend for ballot) on Monday at our 1 pm Eastern Terminology and Ontology WG meeting.

October 8, 2021

The Risk of Bias Terminology and Tooling Working Group reviewed and prepared 13 terms for vote by the Risk of Bias Code System Expert Working Group:

- **Bias (SEVCO:00001) (False Certainty) = A systematic distortion in research results (estimation of effect, association, or inference). Distortions in research results means differences between the reported results (findings, conclusions, effect estimates) and the actuality (the truth, the estimand [the quantity targeted for estimation]).**
- **Detection Bias (SEVCO:00020) = 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 (SEVCO:00042) = A detection bias due to distortions in how an outcome is determined.**
- **Outcome Ascertainment Bias (SEVCO:00058) (Ascertainment bias for outcome determination) = An outcome detection bias due to distortions in how the data are collected.**
    - **Inappropriate follow up period for outcome of interest (SEVCO:00097) [Draft Term] = An outcome ascertainment bias due to differences in the time period used for observation of the outcome and the true time period for outcome occurrence.**
    - **Unreliable method for outcome ascertainment (SEVCO:00098) (Error in data collection not minimized for outcome determination) [Draft Term] = An outcome ascertainment bias due to methods of data collection that result in inconsistent data values.**
    - **Imbalance in application of outcome ascertainment (SEVCO:00099) [Draft Term] = An outcome ascertainment bias due to differences within or between groups in how the data are collected.**
- **Outcome Measurement Bias (SEVCO:00059) (Measurement bias for outcome determination) = An outcome detection bias due to distortions in how the data are measured.**
    - **Outcome measurement method inappropriate (SEVCO:00100) [Draft Term] = An outcome measurement bias due to use of an incorrect method or protocol.**
    - **Insensitive measure bias for outcome determination (SEVCO:00101) (Inadequate sensitivity for outcome measure) [Draft Term] = An outcome measurement bias due to use of a method that does not reliably detect the outcome when the outcome is present. (Comment for application: Use of an inadequately sensitive outcome measure is likely to result in false negative findings.)**
    - **Nonspecific measure bias for outcome determination (SEVCO:00211) (Inadequate specificity for outcome measure) [Draft Term] = An outcome measurement bias due to use of a method that falsely detects the outcome when the outcome is absent. (Comment for application: Use of an inadequately specific outcome measure is likely to result in false positive findings.)**
    - **Outcome measurement method unclear (SEVCO:00102) [Draft Term] = An outcome measurement bias due to use of a method that is not reported with sufficient clarity and detail such that measurement could be replicated.**
    - **Outcome measurement conduct inappropriate (SEVCO:00103) [Draft Term] = An outcome measurement bias due to incorrect application of the method or protocol.**

        - **Imbalance in application of outcome measurement (SEVCO:00104) [Draft Term] = An outcome measurement bias due to differences within or between groups in how the data are measured.**
- **Outcome Classification Bias (SEVCO:00060) (Misclassification bias for outcome determination, Outcome Misclassification Bias) = An outcome detection bias due to distortions in how the data are classified.**
    - **Outcome Classification System Bias (SEVCO:00061) (Definition bias for outcome determination, Outcome definition bias) = An outcome classification bias resulting from the definition or threshold used for outcome classification.**
        - **Nonrepresentative definition for outcome classification (SEVCO:00105) [Draft Term] = An outcome classification system bias due to a definition or threshold that does not represent the outcome of interest.**
            - **Surrogate marker bias for outcome classification (SEVCO:00108) [Draft Term] (Substitution bias for outcome classification) = A nonrepresentative definition for outcome classification due to use of a factor associated with the outcome rather than a direct observation of the outcome.**
        - **Definition not prespecified for outcome classification (SEVCO:00106) [Draft Term] = An outcome classification system bias due to absence of a predetermined definition.**
        - **Definition unclear for outcome classification (SEVCO:00107) [Draft Term] = An outcome classification system bias due to use of a definition that is not reported with sufficient clarity and detail such that classification could be replicated.**
    - **Outcome Classification Process Bias (SEVCO:00062) (Classification process bias for outcome determination) = An outcome classification bias resulting from the application of the method used for outcome classification.**
    - **Incorporation Bias for outcome determination (SEVCO:00063) = An outcome classification bias due to the inclusion of the exposure under investigation in the method or process used for outcome classification.**

October 1, 2021

There are 28 terms to represent Outcome Detection Bias and its subtypes in our current draft Risk of Bias Code System.

1 of these terms is currently out for ballot, and there are 12 terms left that still need draft definitions:

- **Outcome Detection Bias (SEVCO:00042) = A detection bias due to distortions in how an outcome is determined.**

    Cognitive Interpretive Bias for outcome determination (SEVCO:00047) (Perception bias for outcome determination, Subjective interpretive bias for outcome determination, Subjectivity bias for outcome determination) = An outcome detection bias due to the subjective nature of human interpretation.
        - **Lack of blinding for outcome determination (SEVCO:00048) (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. {Comment for application: If the type of bias (lack of blinding during outcome assessment) is not likely to influence the results (e.g. the outcome is objectively measured and not subject to cognitive interpretive bias), the rating corresponding to the type of bias can be "absent" or "no serious concern".}**

        - **Observer bias for outcome determination (SEVCO:00049) = A cognitive interpretive bias for outcome determination due to subjective interpretations in the process of observing and recording information. {Comment for application: Multiple types of bias can overlap. Observer bias is different than lack of blinding with respect to the exposure. Observer bias is about the influence of the observer's interpretation of what they are observing, whether or not the observer is aware of the participant's exposure.}**
- **Confirmation bias for outcome determination (SEVCO:00052) (Diagnostic suspicion bias for outcome determination, Previous opinion bias for outcome determination) = An observer bias for outcome determination due to previous opinions or knowledge of a subject's prior exposures or assessments.**
        - **Recall bias for outcome determination (SEVCO:00050) = 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 (SEVCO:00051) (Hawthorne effect for outcome determination) = A cognitive interpretive bias for outcome determination due to a study participant's responding or behaving differently when aware of being observed.**
        - **Hypothetical assessment bias for outcome determination (SEVCO:00053) (Subjunctivity bias for outcome determination) = A cognitive interpretive bias for outcome determination due to a difference between an individual's report of an imagined or hypothetical response from their actual response. The response may be a behavior or valuation.**
        - **Mimicry bias for outcome determination (SEVCO:00054) = A cognitive interpretive bias for outcome determination due to a misinterpretation of observations that resemble the outcome.**
        - **Unacceptability bias for outcome determination (SEVCO:00057) (Unacceptable disease bias for outcome determination) [Draft Term] = A cognitive interpretive bias for outcome determination due to distortions in response, response values, or recording of responses resulting from perception of the social unacceptability of an outcome.**
- **Outcome Ascertainment Bias (SEVCO:00058) (Ascertainment bias for outcome determination) = An outcome detection bias due to distortions in how the data are collected.**
- **Inappropriate follow up period for outcome of interest (SEVCO:00097) [Draft Term] (Inappropriate time interval between predictor and outcome)**
- **Error in data collection not minimized (SEVCO:00098) [Draft Term]**
- **Imbalance in application of outcome ascertainment (SEVCO:00099) [Draft Term]**
- **Outcome Measurement Bias (SEVCO:00059) (Measurement bias for outcome determination) = An outcome detection bias due to distortions in how the data are measured.**
- **Outcome measurement method inappropriate (SEVCO:00100) [Draft Term]**
- **Insensitive measure bias (SEVCO:00101) [Draft Term]**
- **Outcome measurement method unclear (SEVCO:00102) [Draft Term]**
- **Outcome measurement conduct improper (SEVCO:00103) [Draft Term]**
- **Imbalance in application of outcome measurement (SEVCO:00104) [Draft Term]**
- **Outcome Classification Bias (SEVCO:00060) (Misclassification bias for outcome determination, Outcome Misclassification Bias) = An outcome detection bias due to distortions in how the data are classified.**
- **Outcome Classification System Bias (SEVCO:00061) (Definition bias for outcome determination, Outcome definition bias) = An outcome classification bias resulting from the definition or threshold used for outcome classification.**
- **Nonrepresentative definition (SEVCO:00105) [Draft Term]**
- **Definition not prespecified (SEVCO:00106) [Draft Term]**
- **Definition unclear (SEVCO:00107) [Draft Term]**

- **Surrogate marker bias (SEVCO:00108) [Draft Term] (Substitution game bias)**
- **Outcome Classification Process Bias (SEVCO:00062) (Classification process bias for outcome determination) = An outcome classification bias resulting from the application of the method used for outcome classification.**
- **Incorporation Bias for outcome determination (SEVCO:00063) = An outcome classification bias due to the inclusion of the exposure under investigation in the method or process used for outcome classification.**

Sept 24, 2021

The Risk of Bias Terminology and Tooling Working Group reviewed the ballot and all 4 terms (term sets) were approved (Hypothetical asessment bias for outcome determination, Mimicry bias for outcome determination, Perception bias for outcome determination {added as alternative term for Cognitive interpretive bias for outcome determination), Outcome classification bias {replaced Outcome misclassification bias as preferred term}).

One term was revised and prepared for vote:

- **Bias (SEVCO:00001) (False Certainty) = A systematic distortion in research results (estimation of effect, association, or inference). Distortions in research results means differences between the reported results (findings, conclusions, effect estimates) and the actuality (the truth, the estimand [the quantity targeted for estimation]).**
    - **Outcome Detection Bias (EBMO:00042) = A detection bias due to distortions in how an outcome is determined.**
        - **Unacceptability bias for outcome determination (SEVCO:00047) (Unacceptable disease bias for outcome determination) [Draft Term] = A cognitive interpretive bias for outcome determination due to distortions in response, response values, or recording of responses resulting from perception of social unacceptability of an outcome.**
        - **Cognitive Interpretive Bias for outcome determination (SEVCO:00047) (Perception bias for outcome determination, Subjective interpretive bias for outcome determination, Subjectivity bias for outcome determination) = An outcome detection bias due to the subjective nature of human interpretation.**
    - **Detection Bias (EBMO:00020) = A bias due to distortions in how variable values (data) are determined. {Comment for application: Determination may include ascertainment or assessment (classification or measurement).}**

Sept 17, 2021

The Risk of Bias Terminology and Tooling Working Group reviewed the ballot and 4 of 5 terms were approved (Bias, Confirmation bias for outcome determination, Outcome classification system bias, Incorporation bias for outcome determination). One term (Outcome classification process bias) had one comment which prompted us to suggest revising the "Outcome Misclassification Bias" term to use a preferred term of "Outcome Classification Bias". We then prepared revised terms (changes highlighted for vote) and terms (marked DRAFT) for continued discussion:

- **Bias (SEVCO:00001) (False Certainty) = A systematic distortion in research results (estimation of effect, association, or inference). Distortions in research results means differences between the reported results (findings, conclusions, effect estimates) and the actuality (the truth, the estimand [the quantity targeted for estimation]).**
    - **Outcome Detection Bias (EBMO:00042) = A detection bias due to distortions in how an outcome is determined.**

        - **Hypothetical assessment bias for outcome determination (SEVCO:00053) (Subjunctivity bias for outcome determination) [Draft Term] = A cognitive interpretive bias for outcome determination due to a difference between an individual's report of an imagined or hypothetical response from their actual response. The response may be a behavior or valuation.**
        - **Mimicry bias for outcome determination (SEVCO:00054) [Draft Term] = A cognitive interpretive bias for outcome determination due to a misinterpretation of observations that resemble the outcome.**
        - **Unacceptability bias for outcome determination (SEVCO:00047) (Unacceptable disease bias for outcome determination) [Draft Term] = A cognitive interpretive bias for outcome determination due to distortions in response values, response rates or uptake of tests resulting from an assessment of "unacceptability" of an outcome.**
        - **Cognitive Interpretive Bias for outcome determination (SEVCO:00047) (Perception bias for outcome determination, Subjective interpretive bias for outcome determination, Subjectivity bias for outcome determination) [Draft Term] = An outcome detection bias due to the subjective nature of human interpretation.**
    - **Detection Bias (EBMO:00020) = 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 Classification Bias (EBMO:00060) (Misclassification bias for outcome determination, Outcome Misclassification Bias) [Draft Term] = An outcome detection bias due to distortions in how the data are classified.**
        - **Outcome Classification System Bias (SEVCO:00061) (Definition bias for outcome determination, Outcome definition bias) [Draft Term] = An outcome classification bias resulting from the definition or threshold used for outcome classification.**
        - **Outcome Classification Process Bias (SEVCO:00062) (Classification process bias for outcome determination) [Draft Term] = An outcome classification bias resulting from the application of the method used for outcome classification.**
        - **Incorporation Bias for outcome determination (SEVCO:00063) [Draft Term] = An outcome classification bias due to the inclusion of the exposure under investigation in the method or process used for outcome classification.**

Sept 10, 2021

The Risk of Bias Terminology and Tooling Working Group revised 5 terms for vote:

- **Bias (SEVCO:00001) (False Certainty) = A systematic distortion in research results (estimation of effect, association, or inference). [DRAFT CHANGE: Add...] Distortions in research results means differences between the reported results (findings, conclusions, effect estimates) and the actuality (the truth, the estimand [the quantity targeted for estimation]).**
- **Confirmation bias for outcome determination (SEVCO:00052) (Diagnostic suspicion bias for outcome determination, Previous opinion bias for outcome determination) [Draft Term] = An observer bias for outcome determination due to previous opinions or knowledge of a subject's prior exposures or assessments.**
- **Outcome Classification System Bias (SEVCO:00061) (Definition bias for outcome determination, Outcome definition bias) [Draft Term] = An outcome misclassification bias resulting from the definition or threshold used for outcome classification.**
- **Outcome Classification Process Bias (SEVCO:00062) (Classification process bias for outcome determination) [Draft Term] = An outcome misclassification bias resulting from the application of the method used for outcome classification.**

- **Incorporation Bias for outcome determination (SEVCO:00063) [Draft Term] = An outcome misclassification bias due to the inclusion of the exposure under investigation in the method or process used for outcome classification.**

4 additional terms (marked DRAFT) have been added to the list below for continued discussion:

- **Bias (SEVCO:00001) (False Certainty) = A systematic distortion in research results (estimation of effect, association, or inference). [DRAFT CHANGE: Add...] Distortions in research results means differences between the reported results (findings, conclusions, effect estimates) and the actuality (the truth, the estimand [the quantity targeted for estimation]).**
  - **Outcome Detection Bias (EBMO:00042) = A detection bias due to distortions in how an outcome is determined.**
    - **Observer bias for outcome determination (SEVCO:00049) = A cognitive interpretive bias for outcome determination due to subjective interpretations in the process of observing and recording information. {Comment for application: Multiple types of bias can overlap. Observer bias is different than lack of blinding with respect to the exposure. Observer bias is about the influence of the observer's interpretation of what they are observing, whether or not the observer is aware of the participant's exposure.}**
      - **Confirmation bias for outcome determination (SEVCO:00052) (Diagnostic suspicion bias for outcome determination, Previous opinion bias for outcome determination) [Draft Term] = An observer bias for outcome determination due to previous opinions or knowledge of a subject's prior exposures or assessments.**
    - **Hypothetical assessment bias for outcome determination (SEVCO:00053) (Subjunctivity bias for outcome determination) [Draft Term] = A cognitive interpretive bias for outcome determination due to a difference between an individual's report of an imagined or hypothetical behavior or valuation from their real behavior or valuation.**
    - **Mimicry bias for outcome determination (SEVCO:00054) [Draft Term] = A cognitive interpretive bias for outcome determination due to a misinterpretation of observations that resemble the outcome when the outcome is not present.**
    - **Perception bias for outcome determination (SEVCO:00056) [Draft Term] = A cognitive interpretive bias for outcome determination due to the researcher's or participant's tendency to be subjective about people and events.**
    - **Unacceptability bias for outcome determination (SEVCO:00047) (Unacceptable disease bias for outcome determination) [Draft Term] = A cognitive interpretive bias for outcome determination due to systematic differences in response values, response rates or uptake of tests resulting from a participant's assessment of "unacceptability" of an outcome.**
    - **Cognitive Interpretive Bias for outcome determination (SEVCO:00047) = An outcome detection bias due to the subjective nature of human interpretation.**
  - **Detection Bias (EBMO:00020) = 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 Misclassification Bias (EBMO:00060) (Misclassification bias for outcome determination) = An outcome detection bias due to distortions in how the data are classified.**
  - **Outcome Classification System Bias (SEVCO:00061) (Definition bias for outcome determination, Outcome definition bias) [Draft Term] = An outcome misclassification bias resulting from the definition or threshold used for outcome classification.**
  - **Outcome Classification Process Bias (SEVCO:00062) (Classification process bias for outcome determination) [Draft Term] = An outcome misclassification bias resulting from the application of the method used for outcome classification.**

- **Incorporation Bias for outcome determination (SEVCO:00063) [Draft Term] = An outcome misclassification bias due to the inclusion of the exposure under investigation in the method or process used for outcome classification.**

August 27, 2021

The Risk of Bias group reviewed ballot 22, containing 14 Detection Bias terms. Ten of the terms were added to our complete Risk of Bias code system. Comments received on the other 4 terms were used to refine those definitions so that they could be send out again for vote.

- **Detection Bias (EBMO:00020) [Approved]= 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) [Approved]= A detection bias due to distortions in how an outcome is determined.**

- **Cognitive Interpretive Bias for outcome determination (EBMO:00047) [Approved]= 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) [Approved]= 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)[Approved](Ascertainment bias for outcome determination) = An outcome detection bias due to distortions in how the data are collected.**
- **Outcome Measurement Bias (EBMO:00059)[Approved] (Measurement bias for outcome determination) = An outcome detection bias due to distortions in how the data are measured.**
- **Outcome Misclassification Bias (EBMO:00060) [Approved](Misclassification bias for outcome determination) = An outcome detection bias due to distortions in how the data are classified.**
- **Exposure Detection Bias (EBMO:00043)[Approved]= 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) [Approved]= 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)[Approved] (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 current Risk of Bias code system has been added to a combined document with our other code systems to form the Scientific Evidence Code System. We discussed the best way to keep this information current between the Code system robot template, individual google docs, and word documents that might sync to the google doc. This system is still under construction.

Aug 20, 2021

The question was asked:

What is the minimum number of votes needed to accept a ballot from the expert working group?

Ballot 20 currently has 3 votes.

Ballot 20 was a special ballot to cover Analysis Bias and Bias in selection of the analysis -those terms have not been finalized

Previously we were working on Detection bias terms

Decision was made to ask authors to vote in the meeting. Authors who were present in the meeting were included in the total voting members without submitting a ballot.

Work then continued on detection bias terms. Notes can be seen below:

10 terms for vote – term editors: Brian S. Alper, Harold Lehmann, Joanne Dehnbostel, Kenneth Wilkins, Janice Tufte, Muhammad Afzal

- **Detection Bias = 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 = A detection bias due to distortions in how an outcome is determined.**
    - **Cognitive Interpretive Bias for outcome determination = An outcome detection bias due to subjective properties of the assessor.**
      - Lack of blinding for outcome determination (Lack of blinding during outcome assessment) = A cognitive interpretive bias for outcome determination in which the outcome assessor is aware of the participant's status with respect to the exposure of interest.
      - Observer bias for outcome determination = A cognitive interpretive bias for outcome determination in which the process of observing and recording information includes systematic discrepancies from the truth.
      - Recall bias for outcome determination = A cognitive interpretive bias for outcome determination in which a systematic error is due to differences in accuracy or completeness of recall to memory of past events or experiences.

        - Apprehension bias for outcome determination (Hawthorne effect for outcome determination) = A cognitive interpretive bias for outcome determination in which a study participant responds differently due to being observed.
        - 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 Ascertainment Bias (Ascertainment bias for outcome determination) = An outcome detection bias due to distortions in how the data are collected.**
- **Outcome Measurement Bias (Measurement bias for outcome determination) = An outcome detection bias due to distortions in how the data are measured.**
- **Outcome Misclassification Bias (Misclassification bias for outcome determination) = An outcome detection bias due to distortions in how the data are classified.**
    - Outcome Classification System Bias (Definition bias for outcome determination, Outcome definition bias) = An outcome misclassification bias related to the definition or threshold used for outcome definition.
    - Outcome Classification Process Bias (Classification process bias for outcome determination) = An outcome misclassification bias related to the application of the method used for outcome definition.
    - Incorporation Bias for outcome determination = An outcome misclassification bias related to the inclusion of the exposure under investigation in the method or process used for outcome definition.

- **Exposure Detection Bias = 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 = 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 (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 (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]

Aug 13, 2021

The group skipped to work on definitions of Analysis Bias and Bias in selection of the analysis to facilitate defining Risk of Bias for a letter to NEJM about anticoagulation paper

QUIPS:

The Statistical Analysis and Reporting domain addresses the appropriateness of the study's statistical analysis and completeness of reporting. It helps the assessor judge whether results are likely to be spurious or biased because of analysis or reporting. To make this judgment, the assessor considers the data presented to determine the adequacy of the analytic strategy and model-building process and investigates concerns about selective reporting. Selective reporting is an important issue in prognostic factor reviews because studies commonly report only factors positively associated with outcomes. A study would be considered to have low risk of bias if the statistical analysis is appropriate for the data, statistical assumptions are satisfied, and all primary outcomes are reported.

PROBAST:

Domain 4 (Analysis) covers potential sources of bias in the statistical analysis methods. It assesses aspects related to the choice of analysis method and whether key statistical considerations (for example, missing data) were correctly addressed. Use of inappropriate analysis methods or omission of important statistical considerations increases the potential for bias in the estimated predictive performance of a model.

Preferred Term	**Analysis Bias (EBMO:00021)**
Alternative term(s)	
Parent class	**Bias (EMBO:00001)**

Definition	**A bias related to the analytic process applied to the data.**
Term Definition Editors	**Harold Lehmann, Brian S. Alper, Joanne Dehnbostel, Janice Tufte, Philippe Rocca-Serra, Mhuammad Afzal, Kenneth Wilkins**

Preferred Term	**Bias Related to Selection of Analysis (EBMO:00022)**
Alternative term(s)	**Analysis Selection Bias**
Parent class	**Analysis Bias (EBMO:00021)**
Definition	**An analysis bias due to inappropriate choice of analysis methods before the analysis is applied.**
Term Definition Editors	**Harold Lehmann, Brian S. Alper, Joanne Dehnbostel, Janice Tufte, Philippe Rocca-Serra, Mhuammad Afzal, Kenneth Wilkins**

Aug 6, 2021

The Risk of Bias Terminology and Tooling Working Group focused on the Special Update and Immediate Participation Opportunity. We recognized the primary outcome used the measured variable of "Organ support-free days" while the transformed primary outcome used the measured variable of "Survival to hospital discharge without cardiovascular or respiratory organ support for the first 21 days". We separated our original Evidence Resource into two Evidence Resources. We also discussed details to better describe the model characteristics for these statistics.

July 30, 2021

The group discussed Incorporation Bias for outcome determination and ultimately decided to move it to a position under Outcome Misclassification Bias (Misclassification bias for outcome determination)

Notes from today's discussion:

Incorporation Bias for outcome determination = An outcome detection bias in which

Incorporation Bias- A form of detection bias resulting when the index test and the reference test are not independent of each other.

Index test-

reference test-

-The reference standard includes the diagnostic test which is being investigated.

the index test and the reference test should be independent of each other.

do we need definitions of index and reference tests?-there are probably other biases associated with them

The accuracy of the assessment process is tainted

COB definition background and example-When the results of an index test form part of the reference test in a diagnostic study.

Background

In a diagnostic accuracy study, ideally, the index test and the reference test should be independent of each other.

Incorporation bias is a type of verification bias that occurs when results of the index test form part of the reference test. This occurs most frequently when the reference test is a composite of the results of several tests.

Example

In assessing the diagnostic accuracy of prostate-specific antigen (PSA), in some studies, the PSA results formed part of the reference test in that they were used as part of the final criteria to determine whether participants did or did not have prostate cancer.

For example, verification bias led to an elevation of sensitivity estimates of PSA. The PSA levels should have been excluded from the criteria establishing the presence or absence of disease in the study.

Incorporation Bias

Incorporation bias (eg non-independence of reference standard and index test, systematic errors in measurement of outcome related to intervention received)	4. None of the eligibility criteria were common effects of exposure and outcome22 Confounders should be assessed prior to exposure or treatment initiation to ensure that are not affected by the exposure.23	Cochrane ROB DTA, MASTER-4, ROBINS-I, COB

Here are the drafted terms with highlights for terms that do not have an initial draft definition yet:

- Detection Bias = 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 = A detection bias specific to how the outcome is determined.
- Cognitive Interpretive Bias for outcome determination = An outcome detection bias in which subjective properties of the assessor results in a systematic distortion.

- **Lack of blinding for outcome determination (Lack of blinding during outcome assessment) = A cognitive interpretive bias for outcome determination in which the outcome assessor is aware of the participant's status with respect to the exposure of interest.**
- **Observer bias for outcome determination = A cognitive interpretive bias for outcome determination in which the process of observing and recording information includes systematic discrepancies from the truth.**
- **Recall bias for outcome determination = A cognitive interpretive bias for outcome determination in which a systematic error is due to differences in accuracy or completeness of recall to memory of past events or experiences.**
- **Apprehension bias for outcome determination (Hawthorne effect for outcome determination) = A cognitive interpretive bias for outcome determination in which a study participant responds differently due to being observed.**
- **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.**
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- **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.**
- **Incorporation Bias for outcome determination = An outcome detection bias in which …?drop from first set of terms-moved to position under Outcome Misclassification bias**
- **Outcome Ascertainment Bias (Ascertainment bias for outcome determination) = An outcome detection bias related to how data is collected.**
- **Outcome Measurement Bias (Measurement bias for outcome determination) = An outcome detection bias related to how data is measured.**
- **Outcome Misclassification Bias (Misclassification bias for outcome determination) = An outcome detection bias related to how data is classified.**
- **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 detection bias in which …?drop from first set of terms**
-
- **Exposure Detection Bias = A detection bias specific to how the 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 = A detection bias specific to how the … is determined.**
- **[child terms will be derived following the model developed for Outcome Detection Bias]**

- **Detection Bias related to the Reference Standard (Bias for reference standard result determination) = A detection bias specific to 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 (Bias for index text result determination) = A detection bias specific to how the index text result is determined.**
- **[child terms will be derived following the model developed for Outcome Detection Bias]**

For consideration for Incorporation Bias for outcome determination:

MASTER-4 Safeguard 4. None of the eligibility criteria were common effects of exposure and outcome

ROBINS-I has Classification potentially influenced by risk of outcome

For consideration for Outcome Classification System Bias (Outcome definition bias):

Nonrepresentative definition/threshold	**34. The intervention/exposure period was long enough to have influenced the study outcome22** **35. Dose of intervention/exposure was sufficient to influence the outcome22** **The definition, assessment and timing of predictors in the model match the research question.14** **The outcome, its definition, timing and determination match the research question.14**	**MASTER-34, MASTER-35, PROBAST, QUADAS-2**
Definition/threshold not prespecified	**A pre-specified or standard outcome definition was used.14**	**QUADAS-2, ROBINS-I, PROBAST**
Definition/threshold unclear	**Clearly define exposure prior to study.24**	**Newcastle, ROBINS-I**

Surrogate marker bias (Substitution game bias)	**Avoid using proxies of exposure.24**	**CoB**

For consideration for Outcome Classification Process Bias:

Definition not consistently applied to all participants	**20. Exposure/intervention definition was consistently applied to all participants22** **21. Outcome definition was consistently applied to all participants22**	**MASTER-20, MASTER-21**

July 30, 2021

The group discussed **Incorporation Bias for outcome determination** and ultimately decided to move it to a position under Outcome Misclassification Bias (Misclassification bias for outcome determination)

Notes from today's discussion:

Incorporation Bias for outcome determination = An outcome detection bias in which

Incorporation Bias- A form of detection bias resulting when the index test and the reference test are not independent of each other.

Index test-

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-The reference standard includes the diagnostic test which is being investigated.
the index test and the reference test should be independent of each other.

do we need definitions of index and reference tests?-there are probably other biases associated with them

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COB definition background and example-When the results of an index test form part of the reference test in a diagnostic study.

Background

In a diagnostic accuracy study, ideally, the index test and the reference test should be independent of each other.

Incorporation bias is a type of verification bias that occurs when results of the index test form part of the reference test. This occurs most frequently when the reference test is a composite of the results of several tests.

Example

In assessing the diagnostic accuracy of prostate-specific antigen (PSA), in some studies, the PSA results formed part of the reference test in that they were used as part of the final criteria to determine whether participants did or did not have prostate cancer.

For example, verification bias led to an elevation of sensitivity estimates of PSA. The PSA levels should have been excluded from the criteria establishing the presence or absence of disease in the study.

Incorporation Bias

Incorporation bias (eg non-independence of reference standard and index test, systematic errors in measurement of outcome related to intervention received)	4. None of the eligibility criteria were common effects of exposure and outcome[22] Confounders should be assessed prior to exposure or treatment initiation to ensure that are not affected by the exposure.[23]	Cochrane ROB DTA, MASTER-4, ROBINS-I, COB

Here are the drafted terms with highlights for terms that do not have an initial draft definition yet:

- **Detection Bias = 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 = A detection bias specific to how the outcome is determined.**
    - **Cognitive Interpretive Bias for outcome determination = An outcome detection bias in which subjective properties of the assessor results in a systematic distortion.**
      - **Lack of blinding for outcome determination (Lack of blinding during outcome assessment) = A cognitive interpretive bias for outcome determination in which the outcome assessor is aware of the participant's status with respect to the exposure of interest.**
      - **Observer bias for outcome determination = A cognitive interpretive bias for outcome determination in which the process of observing and recording information includes systematic discrepancies from the truth.**

        - **Recall bias for outcome determination = A cognitive interpretive bias for outcome determination in which a systematic error is due to differences in accuracy or completeness of recall to memory of past events or experiences.**
        - **Apprehension bias for outcome determination (Hawthorne effect for outcome determination) = A cognitive interpretive bias for outcome determination in which a study participant responds differently due to being observed.**
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        - **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.**
    - **Incorporation Bias for outcome determination = An outcome detection bias in which …?drop from first set of terms-moved to position under Outcome Misclassification bias**
    - **Outcome Ascertainment Bias (Ascertainment bias for outcome determination) = An outcome detection bias related to how data is collected.**
    - **Outcome Measurement Bias (Measurement bias for outcome determination) = An outcome detection bias related to how data is measured.**

        - **Outcome Misclassification Bias (Misclassification bias for outcome determination) = An outcome detection bias related to how data is classified.**
            - **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 detection bias in which …?drop from first set of terms**
            -
    - **Exposure Detection Bias = A detection bias specific to how the 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 = A detection bias specific to how the … is determined.**
        - **[child terms will be derived following the model developed for Outcome Detection Bias]**
    - **Detection Bias related to the Reference Standard (Bias for reference standard result determination) = A detection bias specific to 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 (Bias for index text result determination) = A detection bias specific to how the index text result is determined.**
        - **[child terms will be derived following the model developed for Outcome Detection Bias]**

For consideration for Incorporation Bias for outcome determination:

MASTER-4 Safeguard 4. None of the eligibility criteria were common effects of exposure and outcome

ROBINS-I has Classification potentially influenced by risk of outcome

For consideration for Outcome Classification System Bias (Outcome definition bias):

Nonrepresentative definition/threshold	**34. The intervention/exposure period was long enough to have influenced the study outcome**[22] **35. Dose of intervention/exposure was sufficient to influence the outcome**[22] **The definition, assessment and timing of predictors in the model match the research question.**[14] **The outcome, its definition, timing and determination match the research question.**[14]	**MASTER-34, MASTER-35, PROBAST, QUADAS-2**
Definition/threshold not prespecified	**A pre-specified or standard outcome definition was used.**[14]	**QUADAS-2, ROBINS-I, PROBAST**
Definition/threshold unclear	**Clearly define exposure prior to study.**[24]	**Newcastle, ROBINS-I**
Surrogate marker bias (Substitution game bias)	**Avoid using proxies of exposure.**[24]	**CoB**

For consideration for Outcome Classification Process Bias:

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Definition not consistently applied to all participants	**20. Exposure/intervention definition was consistently applied to all participants**[22] **21. Outcome definition was consistently applied to all participants**[22]	**MASTER-20, MASTER-21**

July 23, 2021

The group worked to define a group of terms under detection bias. The current draft of those terms is as follows:

Detection Bias A bias due to distortions in how variable values (data) are determined.

Outcome Detection Bias A detection bias specific to how the outcome is determined.

Cognitive Interpretive Bias for outcome determination An outcome detection bias in which subjective properties of the assessor results in a systematic distortion.

Lack of blinding for outcome determination A cognitive interpretive bias for outcome determination in which the outcome assessor is aware of the participant's status with respect to the exposure of interest

Observer bias for outcome determination A cognitive interpretive bias for outcome determination in which the process of observing and recording information includes systematic discrepancies from the truth.

Recall bias for outcome determination A cognitive interpretive bias for outcome determination in which a systematic error is due to differences in accuracy or completeness of recall to memory of past events or experiences

Apprehension bias for outcome determination A cognitive interpretive bias for outcome determination in which a study participant responds differently due to being observed.

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 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.

EBMO:00020	**Detection Bias**	**EBMO:00001**		**A bias due to distortions in how variable values (data) are determined.**	**Brian S. Alper, Kenneth Wilkins, Joanne Dehnbostel, Philippe Rocca-Serra, Mario Tristan, Harold Lehmann**
EBMO:00042	**Outcome Detection Bias**	**EBMO:00020**		**A detection bias specific to how the outcome is determined.**	**Brian S. Alper, Joanne Dehnbostel, Philippe Rocca-Serra, Mario Tristan, Janice Tufte, Harold Lehmann, Erfan Shamsoddin, Muhammad Afzal**

EBMO:00047	Cognitive Interpretive Bias for outcome determination	EBMO:00042		An outcome detection bias in which subjective properties of the assessor results in a systematic distortion.	Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel
EBMO:00048	Lack of blinding for outcome determination	EBMO:00047	Lack of blinding during outcome assessment	A cognitive interpretive bias for outcome determination in which the outcome assessor is aware of the participant's status with respect to the exposure of interest.	Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel
	Observer bias for outcome determination	EBMO:00047		A cognitive interpretive bias for outcome determination in which the process of observing and recording information includes systematic discrepancies from the truth.	Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel

	Recall bias for outcome determination	**EBMO:00047**		**A cognitive interpretive bias for outcome determination in which a systematic error is due to differences in accuracy or completeness of recall to memory of past events or experiences.**	**Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel**
	Apprehension bias for outcome determination	**EBMO:00047**	**Hawthorne effect for outcome determination**	**A cognitive interpretive bias for outcome determination in which a study participant responds differently due to being observed.**	**Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel**
	Diagnostic suspicion bias for outcome determination	**EBMO:00047**		**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.**	**Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel**

	Hypothetical bias for outcome determination	**EBMO:00047**		**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.**	**Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel**
	Mimicry bias for outcome determination	**EBMO:00047**		**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.**	**Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel**
	Previous opinion bias for outcome determination	**EBMO:00047**		**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.**	**Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel**

	Perception bias for outcome determination	**EBMO:00047**		**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.**	**Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel**
	Unacceptability bias for outcome determination	**EBMO:00047**	**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.**	**Brian S. Alper, Harold Lehmann, Muhammad Afzal, Janice Tufte, Joanne Dehnbostel**

July 16, 2021

Both the Risk of Bias Terminology and Tooling Working Group and the Communications Working Group were excited to view rapid developments and provide feedback for multiple tools on the FEvIR Platform, especially for communication efforts (in preparation for demonstration at the MCBK 2021
https://mobilizecbk.med.umich.edu/news-events/annual-meetings/2021-meeting on July 20-21) to showcase some impact from our COKA efforts.

July 9, 2021

We selected pre-coordinated approach with What-then-How model to be the easiest for the end-user. The pattern in discussion now looks like:

- **Detection Bias = A bias due to distortions in how variable values (data) are determined. [Comments for application: Determination may include ascertainment or assessment (classification or measurement).]**
  - **Outcome Detection Bias = A detection bias specific to how the outcome is determined.**
    - **Cognitive Interpretive Bias for outcome determination**
      - **Cognitive Interpretive Bias due to lack of blinding for outcome determination**
    - **Incorporation Bias for outcome determination**
    - **Outcome Ascertainment Bias (Ascertainment bias for outcome determination)**
    - **Outcome Measurement Bias (Measurement bias for outcome determination)**
    - **Outcome Misclassification Bias (Misclassification bias for outcome determination)**
      - **Outcome Classification System Bias (Definition bias for outcome determination)**
      - **Outcome Classification Process Bias (Classification process bias for outcome determination)**
  - **Exposure Detection Bias = A detection bias specific to how the exposure of interest is determined. [Comments for application: The exposure of interest can be an intervention or a prognostic factor, depending on the research context.]**
    - **[child terms will follow pattern developed for Outcome Detection Bias]**
  - **Confounder Detection Bias**
    - **[child terms will follow pattern developed for Outcome Detection Bias]**
  - **Detection Bias related to the reference standard**
    - **[child terms will follow pattern developed for Outcome Detection Bias]**
  - **Detection Bias related to the index test**
    - **[child terms will follow pattern developed for Outcome Detection Bias]**

For definition mapping:

- **Cognitive Interpretive Bias for outcome determination**
  - **ROB2, ROBINS-I - Assessment of the outcome could not have been influenced by knowledge of intervention received**[18], Standardize interviewer's interaction with patient.[24]
  - CoB has many terms

Observer bias

Recall bias
Apprehension bias (Hawthorne effect)
Diagnostic suspicion bias
Hypothetical bias
Mimicry bias
Previous opinion bias
Perception bias
Unacceptability bias (Unacceptable disease bias)

-
    - **Cognitive Interpretive Bias due to lack of blinding for outcome determination**
        - MASTER-13, MMAT, Newcastle, PROBAST, QUADAS-2, ROB1, ROB2, ROBINS-I
        - Measures were used to blind outcome assessment from knowledge of which intervention a participant received, and intended blinding was effective[17]
        - Outcome assessors were not aware of the intervention received by study participants[18]
        - 13. Outcome assessor(s) were blinded[22]
        - Blind interviewer to exposure status.[24]
        - Predictor assessments were made without knowledge of outcome data.[14]
        - The outcome was determined without knowledge of predictor information.14
- **Incorporation Bias for outcome determination**
    - Cochrane MASTER-4, ROBINS-I, 4. None of the eligibility criteria were common effects of exposure and outcome[22]
    - ROBINS-I has Classification potentially influenced by risk of outcome
- **Outcome Ascertainment Bias (Ascertainment bias for outcome determination)**
    - CoB, MASTER-10, MASTER-36, Newcastle, CoB (Availability Bias)
    - CoB (Diagnostic access bias)
- **Outcome Measurement Bias (Measurement bias for outcome determination)**
    - ROB2, ROBINS-I, CoB (Information Bias)
    -

Inappropriate method	The method of measuring the outcome was appropriate[18] The definition, assessment and timing of predictors in the model match the research question.[14] The outcome, its definition, timing and determination match the research question.[14] The outcome was determined appropriately.[14]	MMAT, Newcastle, PROBAST, QUIPS, ROB2
Insensitive measure bias		CoB
Assessment method unclear		Newcastle, QUIPS
Improper conduct of assessment		QUADAS-2
Incomplete application of assessment		Cochrane ROB DTA, QUADAS-2; CoB (Partial reference bias, Differential reference bias, Verification bias)
Inappropriate follow up period for outcome of interest	36. Length of follow-up was not too long or too short in relation to the outcome assessment[22]	MASTER-36, Newcastle
Inappropriate delay between index test and reference standard		Cochrane ROB DTA, QUADAS-2
Inappropriate time interval between predictor and outcome	The time interval between predictor assessment and outcome determination was appropriate.[14]	PROBAST
Error in data collection not minimized	Efforts were made to minimise error in data collection[20] Use objective data sources whenever possible. When using subjective data sources, corroborate with medical record.[24]	Newcastle, ROBIS

Imbalance in application of method	measurement or ascertainment of the outcome could not have differed between intervention groups[18] Predictors were defined and assessed in a similar way for all participants. [14] The outcome was defined and determined in a similar way for all participants. [14]	Cochrane ROB DTA, Newcastle, PROBAST, QUIPS, ROB2, ROBINS-I

- **Outcome Misclassification Bias (Misclassification bias for outcome determination)**
  - CoB, Newcastle, QUADAS-2, ROBINS-I
  - **Outcome Classification System Bias (Definition bias for outcome determination)**
    -

Nonrepresentative definition/threshold	**34. The intervention/exposure period was long enough to have influenced the study outcome[22]** **35. Dose of intervention/exposure was sufficient to influence the outcome[22]** **The definition, assessment and timing of predictors in the model match the research question.[14]** **The outcome, its definition, timing and determination match the research question.[14]**	**MASTER-34, MASTER-35, PROBAST, QUADAS-2**
Definition/threshold not prespecified	**A pre-specified or standard outcome definition was used.[14]**	**QUADAS-2, ROBINS-I, PROBAST**
Definition/threshold unclear	**Clearly define exposure prior to study.[24]**	**Newcastle, ROBINS-I**

Surrogate marker bias (Substitution game bias)	**Avoid using proxies of exposure.[24]**	**CoB**

- **Outcome Classification Process Bias (Classification process bias for outcome determination)**

Definition not consistently applied to all participants	**20. Exposure/intervention definition was consistently applied to all participants[22]** **21. Outcome definition was consistently applied to all participants[22]**	**MASTER-20, MASTER-21**

- **for supporting materials:**
  - **https://docs.google.com/document/d/1aeI4fb2kMkxWP7HO1GNlyCZ1fLs_rWad**
  - **https://docs.google.com/spreadsheets/d/1_qxV2Snq6YhEQrBcM1rG-95noXJ3TC0m34ZNOcAzqEQ**
  - **https://drive.google.com/drive/folders/1SJgEpmJpDj97vSD5amv-PQutJOR6ujp6**

July 2, 2021

We are discussing the pre-coordination vs. post-coordination approach to the resulting code system. Do you have suggestions which approach is preferable for system implementation? (Note: the end-user could have an easy-to-use system, but the system engineer needs to map to one of these approaches to create the easy-to-use system.)

One approach is a post-coordination approach which may look like:

- **1) Detection Bias terms like:**
  - **Cognitive Interpretive Bias for data determination**
    - **Cognitive Interpretive Bias due to lack of blinding for data determination**
  - **Incorporation Bias for data determination**
  - **Ascertainment Bias**
    - **Ascertainment Availability Bias**
  - **Measurement Bias**
    - **Assessment Method Bias**

    - **Misclassification Bias**
        - **Classification System (Definition) Bias**
        - **Classification Process (Application) Bias**
- **2) Detection Bias Focus Modifier**
    - **Outcome Detection Bias = A detection bias specific to how the outcome is determined.**
    - **Exposure Detection Bias = A detection bias specific to how the exposure of interest is determined. [Comments for application: The exposure of interest can be an intervention or a prognostic factor, depending on the research context.]**
    - **Confounder Detection Bias – not yet defined**
    - **Detection Bias related to the reference standard – not yet defined**
    - **Detection Bias related to the index test – not yet defined**
- **Then you would need a term from group 1 and a term from group 2 to report the combination.**

Another approach is a pre-coordination approach which may look like:

- **Detection Bias = A bias due to distortions in how variable values (data) are determined. [Comments for application: Determination may include ascertainment or assessment (classification or measurement).]**
    - **Cognitive Interpretive Bias for data determination**
        - **Cognitive Interpretive Bias affecting outcome determination**
            - **Cognitive Interpretive Bias due to lack of blinding for outcome determination**
        - **Cognitive Interpretive Bias affecting exposure determination**
            - **Cognitive Interpretive Bias due to lack of blinding for exposure determination**
        - **Cognitive Interpretive Bias affecting confounding determination**
            - **Cognitive Interpretive Bias due to lack of blinding for confounding determination**
        - **Cognitive Interpretive Bias affecting reference standard determination**
            - **Cognitive Interpretive Bias due to lack of blinding to index test results during reference standard determination**
        - **Cognitive Interpretive Bias affecting index test determination**
            - **Cognitive Interpretive Bias due to lack of blinding to reference standard results during index test determination**
        - **….**
    - **Incorporation Bias for data determination**
    - **Ascertainment Bias**
        - **Ascertainment Availability Bias**
    - **Measurement Bias**
        - **Assessment Method Bias**
    - **Misclassification Bias**

        - **Classification System (Definition) Bias**
        - **Classification Process (Application) Bias**

And each of the terms would get discrete mapping to each of the relevant "modifier" concepts.

- **Detection Bias Focus Modifier**
    - **Outcome Detection Bias = A detection bias specific to how the outcome is determined.**
    - **Exposure Detection Bias = A detection bias specific to how the exposure of interest is determined. [Comments for application: The exposure of interest can be an intervention or a prognostic factor, depending on the research context.]**
    - **Confounder Detection Bias – not yet defined**
    - **Detection Bias related to the reference standard – not yet defined**
    - **Detection Bias related to the index test – not yet defined**

Within a pre-coordinated approach we could use either:

1. **How-then-What model ---- the list above that first classifies concepts like Incorporation Bias or Measurement Bias, and then classifies the Outcome/Exposure/etc. focus**
2. **What-then-How model --- the list below that first classifies Outcome Detection Bias/Exposure Detection Bias/etc., and then classifies concepts like Incorporation Bias or Measurement Bias**

June 25, 2021

The Risk of Bias Terminology and Tooling Working Group continued to discuss and revise the hierarchy for terms and definitions for Detection Bias and selected child terms. We will continue this development before sharing the set for vote. Here is the latest version as it takes shape:

- **Detection Bias = A bias due to distortions in how variable values (data) are determined. [Comments for application: Determination may include ascertainment or assessment (classification or measurement).]**
    - **Outcome Detection Bias = A detection bias specific to how the outcome is determined.**
        - **Lack of blinding for outcome assessment**
        - **Cognitive Interpretive Bias for outcome assessment**
        - **Incorporation Bias for outcome assessment**
        - **Outcome Ascertainment Bias**
            - **Outcome Ascertainment Availability Bias**

        - Outcome Measurement Bias
            - Outcome Assessment Method Bias
        - Outcome Misclassification Bias
            - Outcome Classification System (Definition) Bias
            - Outcome Classification Process (Application) Bias
    - Exposure Detection Bias = A detection bias specific to how the exposure of interest is determined. [Comments for application: The exposure of interest can be an intervention or a prognostic factor, depending on the research context.]
        - [child terms will follow pattern developed for Outcome Detection Bias]
    - Confounder Detection Bias
        - [child terms will follow pattern developed for Outcome Detection Bias]
    - Detection Bias related to the reference standard
        - [child terms will follow pattern developed for Outcome Detection Bias]
    - Detection Bias related to the index test
        - [child terms will follow pattern developed for Outcome Detection Bias]

June 18, 2021

The Risk of Bias Terminology and Tooling group reviewed the ballot for the definition of attrition bias. The definition passed unanimously with 13 voters.

We then worked to define the terms under Detection Bias. We have tentative definitions for three terms including the detection bias parent term, but decided to continue with the additional child terms and send them all for a vote at the same time. Details can be seen on our template in the google drive. This work will continue at next week's meeting.

Preferred Term	**Detection Bias (EBMO:00020)**
Alternative term(s)	**None**
Parent class	**Bias (EBMO:00001)**
Definition	
Comment for Application	**None**
Term Definition Editors	

We drafted the following terms and definitions for Detection Bias and selected child terms. We will continue this development before sharing the set for vote.

- **Detection Bias = A bias due to distortions in how variable values (data) are determined. [Comments for application: Determination may include ascertainment or assessment (classification or measurement).]**

o Outcome Detection Bias = A detection bias specific to how the outcome is determined.

Outcome Measurement Bias --- not yet defined, may be considered a child of Outcome Assessment Bias

Outcome Classification Bias --- not yet defined, may be considered a child of Outcome Assessment Bias

Outcome Ascertainment Bias – not yet defined

o Exposure Detection Bias = A detection bias specific to how the exposure of interest is determined. [Comments for application: The exposure of interest can be an intervention or a prognostic factor, depending on the research context.]

o Confounder Detection Bias – not yet defined

o Detection Bias related to the reference standard – not yet defined

o Detection Bias related to the index test – not yet defined

June 11, 2021

The Risk of Bias Terminology and Tooling Working Group reviewed the latest ballot and developed the next one for vote by the Risk of Bias Concept Development Expert Working Group:

Inadequate allocation concealment (EBMO:00031) Passed 10/10

Definition- An allocation bias resulting from awareness of the assigned intervention before study enrolment and intervention assignment.

The following two terms each had one negative vote 9-1, and we agreed to add comments for clarification and are sending them out again for vote.

Preferred Term	**Inadequate blinding of participants (EBMO:00035)**

Alternative term(s)	**Inadequate masking of participants, Lack of blinding of participants**
Parent class	**Performance Bias (EBMO:00017)**
Definition	**A performance bias due to awareness of the allocated intervention by participants.**
Comment for Application	**Inadequate blinding of participants is applied when there is awareness of assigned intervention AFTER intervention assignment. If there is awareness BEFORE study enrolment and intervention assignment, this would be Inadequate allocation concealment.** **The term "Inadequate blinding of participants" is used to denote the TYPE of bias. Separate terms for the RATING of risk of bias are used to report the likelihood of the presence and influence of the type of bias.**
Term Definition Editors	**Brian S. Alper, Joanne Dehnbostel, Muhammad Afzal, Janice Tufte, Erfan Shamsoddin, Bhagvan Kommadi, Philippe Rocca-Serra**

Preferred Term	**Inadequate blinding of intervention deliverers (EBMO:00036)**
Alternative term(s)	**Inadequate masking of intervention deliverers, Lack of blinding of intervention deliverers**
Parent class	**Performance Bias (EBMO:00017)**

Definition	**A performance bias due to awareness of the allocated intervention by individuals providing or delivering the intervention.**
Comment for Application	**Inadequate blinding of intervention deliverers is applied when there is awareness of assigned intervention AFTER intervention assignment. If there is awareness BEFORE study enrolment and intervention assignment, this would be Inadequate allocation concealment.** **The term noted here is used to denote the TYPE of bias. Separate terms for the RATING of risk of bias are used to report the likelihood of the presence and influence of the type of bias.**
Term Definition Editors	**Brian S. Alper, Joanne Dehnbostel, Muhammad Afzal, Janice Tufte, Erfan Shamsoddin, Bhagvan Kommadi, Philippe Rocca-Serra**

We then defined Attrition bias and Detection Bias which will also be sent out for vote:

Preferred Term	**Attrition Bias (EBMO:00019)**
Alternative term(s)	**Missing Data Bias**
Parent class	**Bias (EBMO:00001)**
Definition	**A Bias due to absence of expected participation or data collection after study enrollment.**
Comment for Application	**None**
Term Definition Editors	**Brian S. Alper, Kenneth Wilkins, Joanne Dehnbostel, Philippe Rocca-Serra, Mario Tristan**

Preferred Term	**Detection Bias (EBMO:00020)**
Alternative term(s)	**None**
Parent class	**Bias (EBMO:00001)**
Definition	**A bias due to distortions in how variable values (data) are determined (measured, classified, or ascertained).**
Comment for Application	**None**
Term Definition Editors	**Brian S. Alper, Kenneth Wilkins, Joanne Dehnbostel, Philippe Rocca-Serra, Mario Tristan**

June 4, 2021

The risk of bias group discussed and defined the following terms to be sent to the expert working group for ballot. We will also send a revised ballot for Confounding difference with an additional comment.

- **Performance Bias (EBMO:00017)**

    - **Child of: Bias (EBMO:00001)**
    - **Alternative Terms: Study Exposure Adherence Bias, Intervention Adherence Bias, Compliance Bias, Performance Adherence Bias**
    - **Proposed Definition: A bias resulting from differences between the received exposure and the intended exposure.**
    - **Comments: Such differences could be the administration of additional interventions that are inconsistent with the study protocol, or non-adherence by the interventionalists or study participants to their assigned intervention. Such differences may occur based on assignment to intervention or may occur due to adherence to intervention.**
    - **Potential Contributing Sources to Definition:**
        - **Catalog of bias: Performance bias = Systematic differences in the care provided to members of different study groups other than the intervention under investigation (https://catalogofbias.org/biases/performance-bias/)**
        - **ROB1 (https://www.bmj.com/content/343/bmj.d5928): Performance bias (section header)**
        - **ROB2 (https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool/current-version-of-rob-2?authuser=0):**
            - **ROB2 Domain = Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)**

        - This domain relates to biases that arise when there are deviations from the intended interventions. Such deviations could be the administration of additional interventions that are inconsistent with the trial protocol, failure to implement the protocol interventions as intended, or non-adherence by trial participants to their assigned intervention. Biases that arise due to deviations from intended interventions were referred to as performance biases in the original Cochrane tool for assessing risk of bias in randomized trials.
    - ROB2 (https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool/current-version-of-rob-2?authuser=0):
        - Domain = Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)
        - All deviations from the intended intervention that are inconsistent with the trial protocol and affect the outcome are addressed in relation to the effect of adhering to intervention, regardless of whether they arose because of the trial context. It is sometimes not possible to adjust for all deviations from intended intervention. Therefore, when assessing the effect of adhering to intervention as specified in the trial protocol, review authors should specify, in the preliminary considerations (see section 3), what types of deviations from the intended intervention (departures from the trial protocol) will be examined. These will be one or more of: (1) occurrence of non-protocol interventions that could affect the outcome; (2) failures in implementing the protocol interventions that could affect the outcome; and (3) non-adherence to their assigned intervention by trial participants. For example, the START randomized trial compared immediate with deferred initiation of antiretroviral therapy (ART) in HIV-positive individuals, but 30% of those assigned to deferred initiation started ART earlier than the protocol specified (6). Lodi and colleagues estimated a per-protocol effect that adjusted for these protocol deviations, but not for whether participants continued antiretroviral therapy throughout trial follow-up (7). If such deviations are present, review authors should consider whether appropriate statistical methods were used to adjust for their effects.
    - ROBINS-I (https://drive.google.com/file/d/0B7IQVI0kum0kWldlU1BzRGxnclE/view): Bias due to deviations from intended intervention (section header)
    - MASTER scale (https://doi.org/10.1016/j.jclinepi.2021.01.012): 17. Care was delivered equally to all participants

- Inadequate blinding of participants (EBMO:00035)

- Child of: Performance Bias (EBMO:00017)
- Alternative Terms: Inadequate masking of participants, Lack of blinding of participants
- Proposed Definition: A performance bias due to awareness of the allocated intervention by participants
- Term/Definition Editors: Brian S. Alper, Joanne Dehnbostel, Muhammad Afzal, Janice Tufte, Erfan Shamsoddin, Bhagvan Kommadi
- Potential Contributing Sources to Definition:
    - ROB1 (https://www.bmj.com/content/343/bmj.d5928): Blinding of participants and personnel* - Describe all measures used, if any, to blind trial participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective - Performance bias due to

knowledge of the allocated interventions by participants and personnel during the study (Safeguard = Measures were used to blind trial participants and researchers from knowledge of which intervention a participant received, and intended blinding was effective)
    - ROB2 (https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool/current-version-of-rob-2?authuser=0):
        - 2.1. Were participants aware of their assigned intervention during the trial?
        - If participants are aware of their assigned intervention it is more likely that health-related behaviours will differ between the intervention groups. Blinding participants, most commonly through use of a placebo or sham intervention, may prevent such differences. If participants experienced side effects or toxicities that they knew to be specific to one of the interventions, answer this question 'Yes' or 'Probably yes'.
    - MASTER scale (https://doi.org/10.1016/j.jclinepi.2021.01.012): 14. Participants were blinded

- Inadequate blinding of intervention deliverers (EBMO:00036)

- Child of: Performance Bias (EBMO:00017)
- Alternative Terms: Inadequate masking of intervention deliverers, Lack of blinding of intervention deliverers
- Proposed Definition: A performance bias due to awareness of the allocated intervention by individuals providing or delivering the intervention
- Term/Definition Editors: Brian S. Alper, Joanne Dehnbostel, Muhammad Afzal, Janice Tufte, Erfan Shamsoddin, Bhagvan Kommadi
- Potential Contributing Sources to Definition:
    - ROB1 (https://www.bmj.com/content/343/bmj.d5928): Blinding of participants and personnel* - Describe all measures used, if any, to blind trial participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective - Performance bias due to knowledge of the allocated interventions by participants and personnel during the study (Safeguard = Measures were used to blind trial participants and researchers from knowledge of which intervention a participant received, and intended blinding was effective)
    - ROB2 (https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool/current-version-of-rob-2?authuser=0):
        - 2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?
        - If carers or people delivering the interventions are aware of the assigned intervention then its implementation, or administration of non-protocol interventions, may differ between the intervention groups. Blinding may prevent such differences. If participants experienced side effects or toxicities that carers or people delivering the interventions knew to be specific to one of the interventions, answer question 'Yes' or 'Probably yes'. If randomized allocation was not concealed, then it is likely that carers and people delivering the interventions were aware of participants' assigned intervention during the trial.

- MASTER scale (https://doi.org/10.1016/j.jclinepi.2021.01.012): 15. Caregivers were blinded

- Deviations from study intervention protocol (EBMO:00037)

- Child of: Performance Bias (EBMO:00017)
- Alternative Terms: None
- Proposed Definition: A performance bias in which the intervention received differs from the intervention specified in the study protocol
- Term/Definition Editors: Brian S. Alper, Joanne Dehnbostel, Muhammad Afzal, Janice Tufte, Erfan Shamsoddin, Bhagvan Kommadi
- Potential Contributing Sources to Definition:
    - ROB2 (https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool/current-version-of-rob-2?authuser=0):
        - 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?
            - For the effect of assignment to intervention, this domain assesses problems that arise when changes from assigned intervention that are inconsistent with the trial protocol arose because of the trial context. We use the term trial context to refer to effects of recruitment and engagement activities on trial participants and when trial personnel (carers or people delivering the interventions) undermine the implementation of the trial protocol in ways that would not happen outside the trial. For example, the process of securing informed consent may lead participants subsequently assigned to the comparator group to feel unlucky and therefore seek the experimental intervention, or other interventions that improve their prognosis.
            - Answer 'Yes' or 'Probably yes' only if there is evidence, or strong reason to believe, that the trial context led to failure to implement the protocol interventions or to implementation of interventions not allowed by the protocol.
            - Answer 'No' or 'Probably no' if there were changes from assigned intervention that are inconsistent with the trial protocol, such as non-adherence to intervention, but these are consistent with what could occur outside the trial context.
            - Answer 'No' or 'Probably no' for changes to intervention that are consistent with the trial protocol, for example cessation of a drug intervention because of acute toxicity or use of additional interventions whose aim is to treat consequences of one of the intended interventions.
            - If blinding is compromised because participants report side effects or toxicities that are specific to one of the interventions, answer 'Yes' or 'Probably yes' only if there were changes from assigned intervention that

are inconsistent with the trial protocol and arose because of the trial context.
        - The answer 'No information' may be appropriate, because trialists do not always report whether deviations arose because of the trial context.
    - 2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups? (effect of adherence)
        - This question is asked only if the preliminary considerations specify that the assessment will address imbalance of important non-protocol interventions between intervention groups. Important non-protocol interventions are the additional interventions or exposures that: (1) are inconsistent with the trial protocol; (2) trial participants might receive with or after starting their assigned intervention; and (3) are prognostic for the outcome. Risk of bias will be higher if there is imbalance in such interventions between the intervention groups.
- ROBINS-I (https://drive.google.com/file/d/0B7IQVI0kum0kWldlU1BzRGxnclE/view): Bias due to deviations from intended intervention (section header)
- MMAT (http://mixedmethodsappraisaltoolpublic.pbworks.com/w/file/fetch/127916259/MMAT_2018_criteria-manual_2018-08-01_ENG.pdf): 3.5. During the study period, is the intervention administered (or exposure occurred) as intended?
- MASTER scale (https://doi.org/10.1016/j.jclinepi.2021.01.012): 8. Exposure variations/treatment deviations were less than 20%

- Deviations from standard of care (EBMO:00038)

- Child of: Performance Bias (EBMO:00017)
- Alternative Terms: None
- Proposed Definition: A performance bias in which the intervention or exposure received differs from the from the usual practice or expected care
- Term/Definition Editors: Brian S. Alper, Joanne Dehnbostel, Muhammad Afzal, Janice Tufte, Erfan Shamsoddin, Bhagvan Kommadi
- Potential Contributing Sources to Definition:
    - ROBINS-I (https://drive.google.com/file/d/0B7IQVI0kum0kWldlU1BzRGxnclE/view): 4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?
    - MMAT (http://mixedmethodsappraisaltoolpublic.pbworks.com/w/file/fetch/127916259/MMAT_2018_criteria-manual_2018-08-01_ENG.pdf): 3.5. During the study period, is the intervention administered (or exposure occurred) as intended?
    - MASTER scale (https://doi.org/10.1016/j.jclinepi.2021.01.012): 8. Exposure variations/treatment deviations were less than 20%

- Nonadherence of Implementation (EBMO:00039)

- **Child of: Performance Bias (EBMO:00017)**
- **Alternative Terms: Nonadherence of interventionalist**
- **Proposed Definition: A performance bias in which the intervention deliverers do not completely adhere to the expected intervention**
- **Term/Definition Editors: Brian S. Alper, Joanne Dehnbostel, Muhammad Afzal, Janice Tufte, Erfan Shamsoddin, Bhagvan Kommadi**
- **Potential Contributing Sources to Definition:**
    - **Catalog of bias: Compliance bias = Participants compliant with an intervention differ in some way from those not compliant which can systematically affect the outcome of interest. (https://catalogofbias.org/biases/compliance-bias/)**
    - **ROB2 (https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool/current-version-of-rob-2?authuser=0):**
        - **2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome? (effect of adherence)**
        - **This question is asked only if the preliminary considerations specify that the assessment will address failures in implementing the intervention that could have affected the outcome. Risk of bias will be higher if the intervention was not implemented as intended by, for example, the health care professionals delivering care. Answer 'No' or 'Probably no' if implementation of the intervention was successful for most participants.**
    - **ROBINS-I (https://drive.google.com/file/d/0B7IQVI0kum0kWldlU1BzRGxnclE/view): 4.4. Was the intervention implemented successfully for most participants?**

- **Nonadherence of Participants (EBMO:00040)**

- **Child of: Performance Bias (EBMO:00017)**
- **Alternative Terms: None**
- **Proposed Definition: A performance bias in which the participants do not completely adhere to the expected intervention or exposure**
- **Term/Definition Editors: Brian S. Alper, Joanne Dehnbostel, Muhammad Afzal, Janice Tufte, Erfan Shamsoddin, Bhagvan Kommadi**
- **Potential Contributing Sources to Definition:**
    - **Catalog of bias: Compliance bias = Participants compliant with an intervention differ in some way from those not compliant which can systematically affect the outcome of interest. (https://catalogofbias.org/biases/compliance-bias/)**
    - **ROB2 (https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool/current-version-of-rob-2?authuser=0):**
        - **2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?**
        - **This question is asked only if the preliminary considerations specify that the assessment will address non-adherence that could have affected participants' outcomes. Non-adherence includes imperfect compliance with a sustained intervention, cessation of intervention, crossovers to the comparator intervention and switches to another active intervention. Consider available information on the proportion of study participants who continued with their assigned intervention**

throughout follow up, and answer 'Yes' or 'Probably yes' if the proportion who did not adhere is high enough to raise concerns. Answer 'No' for studies of interventions that are administered once, so that imperfect adherence is not possible, and all or most participants received the assigned intervention.

- ROBINS-I (https://drive.google.com/file/d/0B7IQVI0kum0kWldlU1BzRGxnclE/view): 4.5. Did study participants adhere to the assigned intervention regimen?
- MMAT (http://mixedmethodsappraisaltoolpublic.pbworks.com/w/file/fetch/127916259/MMAT_2018_criteria-manual_2018-08-01_ENG.pdf):
    - 2.5 Did the participants adhere to the assigned intervention?
    - Explanations
    - To judge this criterion, consider the proportion of participants who continued with their assigned intervention throughout follow-up. "Lack of adherence includes imperfect compliance, cessation of intervention, crossovers to the comparator intervention and switches to another active intervention." (Higgins et al., 2016, p. 25).

- Imbalance in deviations from intended interventions (EBMO:00041)

- Child of: Performance Bias (EBMO:00017)
- Alternative Terms: Asymmetry in adherence between groups
- Proposed Definition: A performance bias in which the degree of performance bias is unequally distributed between groups being compared
- Term/Definition Editors: Brian S. Alper, Joanne Dehnbostel, Muhammad Afzal, Janice Tufte, Erfan Shamsoddin, Bhagvan Kommadi
- Potential Contributing Sources to Definition:
    - ROB2 (https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool/current-version-of-rob-2?authuser=0):
        - 2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?
        - Changes from assigned intervention that are inconsistent with the trial protocol and arose because of the trial context are more likely to impact on intervention effect estimate if they are not balanced between the intervention groups.
    - ROBINS-I (https://drive.google.com/file/d/0B7IQVI0kum0kWldlU1BzRGxnclE/view):
        - 4.2 Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?
        - 4.3. Were important co-interventions balanced across intervention groups?
    - MASTER scale (https://doi.org/10.1016/j.jclinepi.2021.01.012): 17. Care was delivered equally to all participants

May 28, 2021

The group discussed the recent risk of bias ballot and decided to add comments to the next ballot for confounding difference but not to change the definition based on the comment given.

Before sending out an additional ballot for the term performance bias, we decided to clarify and define a family of terms to send out together to give context for the term.

The group discussed performance bias and consolidated the list of terms related to performance bias to include the following:

Performance Bias

Inadequate blinding of participants (Lack of blinding, Inadequate masking)

Inadequate blinding of intervention deliverers (Lack of blinding, Inadequate masking)

Study Exposure Adherence Bias (Intervention Adherence Bias, Compliance Bias, Performance Adherence Bias)

Deviations from study intervention protocol

Deviations from standard of care

Nonadherence of Implementation (Nonadherence of interventionalist)

Nonadherence of Participants

Imbalance in deviations from intended interventions (Asymmetry in adherence between groups)

May 7, 2021

The Risk of Bias Terminology and Tooling Working group discussed the results of Risk of Bias Ballot 12. There were 6 votes on the ballot for three different terms. None of the terms were unanimously accepted by the group.

The three terms on the ballot were:

- **Comparator Bias,**
- **Comparator Selection Bias and**
- **Recognized difference with potential for confounding.**

the votes were 4/2, 5/1 and 5/1 respectively.

Further discussion of these terms led to the following revised terms which will be submitted for ballot today:

Confounding Covariate Bias

Allocation Bias

Details of our Risk of Bias code system work can be found in the Code system robot template.

April 30, 2021

Risk of Bias Terminology and Tooling Working group

Today the risk of bias group discussed the definition of "Comparator Selection Bias". We had a good discussion to help distinguish this from participant selection bias. We set the scope for this term and the definition is close to being ready for ballot.

Preferred Term	**Comparator Selection Bias (EBMO:00016)**

Alternative term(s)	**Allocation Bias, Group Assignment Bias**
Parent class	**Bias (EBMO:00001)**
Definition and supporting information	**TENTATIVE DEFINITION: A bias resulting from differences (other than the variables directly involved in the analysis) between the groups being compared.** **CoB: Allocation bias = Systematic difference in how participants are assigned to comparison groups in a clinical trial. (https://catalogofbias.org/biases/allocation-bias/)** **ROB2 = If successfully accomplished, randomization avoids an influence of either known or unknown prognostic factors (factors that predict the outcome, such as severity of illness or presence of comorbidities) on intervention group assignment. This means that, on average, the intervention groups have the same prognosis before the start of intervention. If prognostic factors influence the intervention group to which participants are assigned then the estimated effect of intervention will be biased by 'confounding', which occurs when there are common causes of intervention group assignment and outcome. Confounding is an important potential cause of bias in intervention effect estimates from observational studies, because treatment decisions in routine care are often influenced by prognostic factors.** **ROBINS-I = Bias due to confounding (section header)**
Term Definition Editors	**Brian S. Alper, Harold Lehmann, Joanne Dehnbostel, Philippe Rocca-Serra, Muhammad Afzal**

April 23,2021

The Risk of Bias Terminology and Tooling Working Group updated the Code System Robot Template with the following top-level classes for Risk of Bias terms and finished mapping definitions/background information from the identified sources for these terms:

Study Selection Bias
Comparator Selection Bias
Performance Bias
Performance Adherence Bias
Attrition Bias
Detection Bias
Analysis Bias
Analysis Selection Bias
Reporting Bias
Selective Analysis Reporting Bias
Interpretive Reporting Bias
Synthesis Bias

Conflicted Interests Bias
Qualitative Research Bias
Mixed Methods Research Bias
Predictive Model Research Bias
Choice-of-Question Bias

With that set completed we then drafted the definition of the term "Study Selection Bias". For this term we reviewed the definitions for Selection Bias and Participant Selection Bias and derived the following which will be sent out today for vote:

Preferred Term	**Study Selection Bias (EBMO:00015)**
Alternative term(s)	**None**
Parent class	**Selection Bias (EBMO:00002)**

Definition	**A selection bias resulting from factors that influence study selection, from methods used to include or exclude studies for evidence synthesis, or from differences between the study sample and the population of interest**
Term Definition Editors	**Brian S. Alper, Harold Lehmann, Joanne Dehnbostel, Khalid Shahin, Muhammad Afzal, Philippe Rocca-Serra**

April 16, 2021

The Risk of Bias Terminology and Tooling Working Group continued to fill in the robot template for the risk of bias code system. Now that we have completed the participant selection bias “branch”, we decided to proceed with the upper level terms and then work toward greater granularity after these are defined. We then proceeded to collect background information on those terms. This information will be used to define terms at next week’s meeting.

April 2, 2021

The Risk of Bias Terminology and Tooling Working Group drafted content for votes for 3 Risk of Bias terms:

- **Post-baseline factors influence enrollment selection (EBMO:00009)**
    - **Child of: Participant Selection Bias (EBMO:00003)**
    - **Alternative terms: Participant selection bias due to post-baseline factors**
    - **Definition: A selection bias in which factors observed after study entry, baseline, or start of follow-up influence enrollment.**
    - **Term/Definition Editors: Brian S. Alper, Joanne Dehnbostel, Philippe Rocca-Serra, Marc Duteau, Khalid Shahin, Asiyah Yu Lin, Harold Lehmann, Mario Tristan**

- **Factor associated with exposure influences enrollment selection (EBMO:00010)**
    - **Child of: Participant Selection Bias (EBMO:00003)**

- Alternative terms: Participant selection bias due to factor associated with exposure
- Definition: A selection bias in which a factor associated with the exposure under investigation influences study enrollment.
- Term/Definition Editors: Brian S. Alper, Joanne Dehnbostel, Khalid Shahin, Harold Lehmann, Mario Tristan, Bhagvan Kommadi, Muhammad Afzal

- Factor associated with outcome influences enrollment selection (EBMO:00011)
  - Child of: Participant Selection Bias (EBMO:00003)
  - Alternative terms: Participant selection bias due to factor associated with outcome
  - Definition: A selection bias in which a factor associated with the outcome under investigation influences study enrollment.
  - Term/Definition Editors: Brian S. Alper, Joanne Dehnbostel, Khalid Shahin, Harold Lehmann, Mario Tristan, Bhagvan Kommadi, Muhammad Afzal

March 26, 2021

The group discussed the results of ballot 6 for the risk of bias term insufficient enrollment. The definition was not accepted with 8/10 voting for the definition. The rest of the meeting was used to redefine insufficient enrollment which resulted in reversion to the previous term name -Inadequate enrollment of eligible subjects.

The terms discussed so far fit into the following hierarchy:

Bias

Selection Bias

Participant selection bias

Inappropriate selection criteria

Inappropriate sampling strategy

Non representative sample

inadequate enrollment of eligible subjects

alt term- Non representative sample due to inadequate enrollment

alt term-Selection bias due to inadequate enrollment

Study selection bias

Notes showing the evolution of definitions discussed are below:

A selection bias in which insufficient enrollment of eligible subjects results in differences (recognized or unrecognized) between the included participants and the population of interest that distorts the research results.

(Exclusion of eligible participants)

Non representative sample due to inadequate participation by eligible participants

Previous name-Inadequate participation by eligible persons

inappropriate (insufficient) enrollment

insufficient enrollment

A selection bias due to eligible subjects participation that is not sufficient for the included sample to be considered representative of the population of interest.

A selection bias due to a level of participation rate (proportion of eligible subjects who enter the study) that is not sufficient for the included sample to be considered representative of the population of interest.

A selection bias in which insufficient enrollment of eligible subjects results in differences between the included participants and the population of interest that distorts the research results.

March 19, 2021

Results for Risk of Bias Ballot 4 and changes to create ballot 5

Participant selection bias:

11 votes -10 yes/1 no

Definition: A selection bias resulting from ...

This results in the following definition with one word change:

"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."

Preferred Term	**Participant Selection Bias (EBMO:00003)**
Alternate term(s)	**[none]**
Parent Class	**Selection Bias (EBMO:00002)**
Definition	**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.**
Term definition editors	**Philippe Rocca-Serra, Brian S. Alper, Marc Duteau, Asiyah Lin, Harold Lehmann, Joanne Dehnbostel**

Non-representative sample:

11 votes 10 yes/1 no

Definition: Selection bias due to differences between...

"A selection bias due to differences between the included participants and the target population that distorts the research results (estimation of effect, association, or inference), limiting external validity or applicability."

Preferred Term	**Non-representative sample (EBMO:00006)**
Alternate term(s)	**Selection bias due to non-representative sample, Unrepresentative sample, Nonrepresentative sample**
Parent Class	**Participant Selection Bias (EBMO:00003)**
Definition	**A selection bias due to differences between the included participants and the population of interest that distorts the research results (estimation of effect, association, or inference), limiting external validity or applicability.**
Term definition editors	**Brian S. Alper, Tatyana Shamliyan, Bhagvan Kommadi, Muhammad Afzal, Khalid Shahin, Philippe Rocca-Serra, Asiyah Lin, Harold Lehmann, Joanne Dehnbostel**

Inappropriate Selection Criteria

11 votes 9 yes/ 2 no

Definition: A selection bias resulting from...

We need to find a better word than "unrepresentative".

"A selection bias resulting from inclusion and exclusion criteria used to select participating subjects that could make the included participants unrepresentative of the population of interest."

Possible changes for unrepresentative:

1) A selection bias resulting from inclusion and exclusion criteria used to select participating subjects that could make the included participants misrepresent the population of interest.

2) A selection bias resulting from inclusion and exclusion criteria used to select participating subjects that could make the included participants not representative of the population of interest.

3) "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."

The group chose option number 3

Preferred Term	**Inappropriate Selection Criteria (EMBO:00004)**
Alternate term(s)	**Selection bias due to inappropriate selection criteria**
Parent Class	**Participant Selection Bias (EBMO:00003)**
Definition	**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.**
Term definition editors	**Brian S. Alper, Tatyana Shamliyan, Bhagvan Kommadi, Muhammad Afzal, Khalid Shahin, Philippe Rocca-Serra, Asiyah Lin, Harold Lehmann, Joanne Dehnbostel**

Inappropriate Sampling Strategy

11 votes 9 yes/2 no

Definition: A selection bias resulting from...

We need to find a better word than "unrepresentative".

suggestion-sample frame and sampling frame seem to be used synonymously and sampling frame is more commonly used

add JD to editors

"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.

New alternative term suggested: inappropriate sampling frame"

Preferred Term	**Inappropriate Sampling Strategy (EBMO:00005)**
Alternate term(s)	**Biased sampling Strategy, Inappropriate sampling frame, Inappropriate sample frame, Inappropriate sampling procedure, Selection bias due to inappropriate sampling strategy**
Parent Class	**Participant Selection Bias (EBMO:00003)**
Definition	**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.**
Term definition editors	**Brian S. Alper, Tatyana Shamliyan, Bhagvan Kommadi, Muhammad Afzal, Khalid Shahin,**

	Philippe Rocca-Serra, Asiyah Lin, Harold Lehmann, Joanne Dehnbostel

New Term discussed-Inadequate participation by eligible persons:

Material from existing tools discussed and used to create the new definition:

From QUIPS-

"To make this judgment, the assessor considers the

proportion of eligible persons who participate in the study,"…

"A study would be considered as

having high risk of bias if the participation rate is low"…

"1a. Adequate participation in the study by eligible persons"

Is this truly a selection bias and a participant selection bias?

Is this a child of non-representative sample?

-The group decided that yes, it is a participant selection bias (the only other place it could go was analysis bias)

and that it should remain a sibling, not a child of non-representative sample.

Preferred Term	**Inadequate participation by eligible persons**
Alternate term(s)	
Parent Class	**Participant Selection Bias**
Definition	

Term definition editors

March 12, 2021

Earlier this week we reviewed the votes on the term ‘Participant Selection Bias’:

2021-03-08 vote 7-2 on "A selection bias where key characteristics of the participants differ systematically from the population of interest." by Harold Lehmann, Philippe Rocca-Serra, Joanne Dehnbostel

A revised definition was created with:

Participant Selection Bias = A 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.

Definition created by Philippe Rocca-Serra, Brian S. Alper, Marc Duteau, Asiyah Lin, Harold Lehmann, Joanne Dehnbostel.

The term Participant Selection Bias (EBMO:00003) is a child of Selection Bias (EBMO:00002) which is child of Bias (EBMO:00001).

The next proposed term is Inappropriate selection criteria (EBMO:00004) which is a child of Participant Selection Bias (EBMO:00003). No alternative terms identified.

Suggested definition:

Inappropriate Selection Criteria = A bias resulting from inclusion and exclusion criteria used to select participating subjects that could make the included participants unrepresentative of the target population.

Definition created by Brian S. Alper, Tatyana Shamliyan, Bhagvan Kommadi, Muhammad Afzal, Khalid Shahin.

Concepts in source material include:

- Newcastle: Case-contol Q1) Is the Case Definition Adequate?
- QUIPS: 1b. Description of the source population or population of interest, 1f. Adequate description of inclusion and exclusion criteria

- PROBAST: "In summary, the key issue is whether any inclusion or exclusion criteria, or the recruitment strategy, could have made the included study participants unrepresentative of the intended target population." (https://www.acpjournals.org/doi/10.7326/M18-1377)
- QUADAS: "Studies that make inappropriate exclusions, e.g. excluding “difficult to diagnose” patients, may result in overoptimistic estimates of diagnostic accuracy. In a review of anti-CCP antibodies for the diagnosis of rheumatoid arthritis, we found that some studies enrolled consecutive patients who had confirmed diagnoses. These studies showed greater sensitivity of the anti-CCP test than studies that included patients with suspected disease but in whom the diagnosis had not been confirmed – “difficult to diagnose” patients.(4) Similarly, studies enrolling patients with known disease and a control group without the condition may exaggerate diagnostic accuracy.(5;6) Exclusion of patients with “red flags” for the target condition, who may be easier to diagnose, may lead to underestimation of diagnostic accuracy." (http://www.bristol.ac.uk/media-library/sites/quadas/migrated/documents/background-doc.pdf)
- Cochrane Handbook for DTA Reviews: "Was the spectrum of patients representative of the patients who will receive the test in practice? (representative spectrum) There are two aspects to this item, first whether the right patient group was recruited to the study to address the review question, and second whether the method of sampling patients for inclusion from this group was likely to yield a representative sample. Studies which differ in the demographic and clinical characteristics of samples may produce measures of diagnostic accuracy that can vary considerably (Ransohoff 1978, Mulherin 2002). Whether the right patient group has been selected can be assessed both by looking at the study inclusion and exclusion criteria, and the tables of characteristics of the recruited sample. Particular characteristics to look out for include patient demographics, severity of disease/symptoms, alternative diseases, co-morbid conditions, healthcare setting, prevalence, and selection based on prior test results." (https://methods.cochrane.org/sites/methods.cochrane.org.sdt/files/public/uploads/ch09_Oct09.pdf)

The next proposed term is Inappropriate sampling strategy (EBMO:00005) which is a child of Participant Selection Bias (EBMO:00003). An alternative term identified include Biased sampling strategy.

Suggested definition:

Inappropriate Sampling Strategy = A bias resulting from the sample frame, sampling procedure, or methods used to recruit participating subjects that could make the included participants unrepresentative of the target population.

Definition created by Brian S. Alper, Tatyana Shamliyan, Bhagvan Kommadi, Muhammad Afzal, Khalid Shahin.

Concepts in source material include:

- Newcastle: case definition does not include independent validation
- QUIPS: 1d. Adequate description of the sampling frame and recruitment, 1e. Adequate description of the period and place of recruitment
- PROBAST: "Prognostic model studies are at low ROB when based on a prospective longitudinal cohort design, where methods tend to be defined and consistently applied for participant inclusion and exclusion criteria, predictor assessment, and outcome determination across a predefined follow-up. Model development and validation studies have higher potential for ROB when participant data are from existing sources, such as existing cohort studies or routine care registries, because data are often collected for a purpose other than development, validation, or updating of prediction models, and are also often without a protocol." (https://www.acpjournals.org/doi/10.7326/M18-1377)
- QUADAS: "A study should ideally enrol all consecutive, or a random sample of, eligible patients with suspected disease – otherwise there is potential for bias. " (http://www.bristol.ac.uk/media-library/sites/quadas/migrated/documents/background-doc.pdf)
- MMAT: "4.1. Is the sampling strategy relevant to address the research question? Sampling strategy refers to the way the sample was selected. There are two main categories of sampling strategies: probability sampling (involve random selection) and non-probability sampling. Depending on the research question, probability sampling might be preferable. Nonprobability sampling does not provide equal chance of being selected. To judge this criterion, consider whether the source of sample is relevant to the target population; a clear justification of the sample frame used is provided; or the sampling procedure is adequate." (http://mixedmethodsappraisaltoolpublic.pbworks.com/w/file/fetch/127916259/MMAT_2018_criteria-manual_2018-08-01_ENG.pdf)
- Cochrane Handbook for DTA Reviews: "Was the spectrum of patients representative of the patients who will receive the test in practice? (representative spectrum) There are two aspects to this item, first whether the right patient group was recruited to the study to address the review question, and second whether the method of sampling patients for inclusion from this group was likely to yield a representative sample. Additionally, the methods used to sample patients for the study may lead to the inclusion of patients different from the spectrum in which the test will be used in practice. The ideal diagnostic accuracy study would prospectively include a consecutive series of patients fulfilling all selection criteria. Such a study is often referred to as a consecutive series study" (https://methods.cochrane.org/sites/methods.cochrane.org.sdt/files/public/uploads/ch09_Oct09.pdf)

The next proposed term is Non-representative sample (EBMO:00006) which is a child of Participant Selection Bias (EBMO:00003). Alternative terms identified include unrepresentative sample and nonrepresentative sample.

Suggested definition:

Non-representative sample = Differences between the included participants and the target population that distorts the research results (estimation of effect, association, or inference), limiting external validity or applicability.

Definition created by Brian S. Alper, Tatyana Shamliyan, Bhagvan Kommadi, Muhammad Afzal, Khalid Shahin.

Concepts in source material include:

- Newcastle: Case-contol Q2) Representativeness of the Cases, Cohort Q2) Representativeness of the Exposed Cohort
- QUIPS: 1c. Description of the baseline study sample
- PROBAST: "Included participants, the selection criteria used as well as the setting used in the primary prediction model study should be relevant to the review question. Applicability for this domain considers the extent to which the population included in the primary study matches the participants specified in the systematic review question" (https://www.acpjournals.org/doi/10.7326/M18-1377)
- QUADAS: "Applicability: Are there concerns that the included patients and setting do not match the review question? There may be concerns regarding applicability if patients included in the study differ, compared to those targeted by the review question, in terms of severity of the target condition, demographic features, presence of differential diagnosis or co-morbidity, setting of the study and previous testing protocols." (http://www.bristol.ac.uk/media-library/sites/quadas/migrated/documents/background-doc.pdf)
- MMAT: "3.1. Are the participants representative of the target population?

  Indicators of representativeness include: clear description of the target population and of the sample (inclusion and exclusion criteria), reasons why certain eligible individuals chose not to participate, and any attempts to achieve a sample of participants that represents the target population.

  4.2. Is the sample representative of the target population?

  There should be a match between respondents and the target population. Indicators of representativeness include: clear description of the target population and of the sample (such as respective sizes and inclusion and exclusion criteria), reasons why certain eligible individuals chose not to participate, and any attempts to achieve a sample of participants that represents the target population." (http://mixedmethodsappraisaltoolpublic.pbworks.com/w/file/fetch/127916259/MMAT_2018_criteria-manual_2018-08-01_ENG.pdf)

- Cochrane Handbook for DTA Reviews: "Was the spectrum of patients representative of the patients who will receive the test in practice? (representative spectrum)

  There are two aspects to this item, first whether the right patient group was recruited to the study to address the review question, and second whether the method of sampling patients for

inclusion from this group was likely to yield a representative sample. Studies which differ in the demographic and clinical characteristics of samples may produce measures of diagnostic accuracy that can vary considerably (Ransohoff 1978, Mulherin 2002). Whether the right patient group has been selected can be assessed both by looking at the study inclusion and exclusion criteria, and the tables of characteristics of the recruited sample. Particular characteristics to look out for include patient demographics, severity of disease/symptoms, alternative diseases, co-morbid conditions, healthcare setting, prevalence, and selection based on prior test results."
(https://methods.cochrane.org/sites/methods.cochrane.org.sdt/files/public/uploads/ch09_Oct09.pdf)

March 5, 2021

We started the meeting by reviewing the results of our expert working group ballot for the definition of "selection bias". The definition on the ballot was approved by 8/8 EWG members that voted, so selection bias now has the following definition:

Selection bias-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

Ideas leading to the creation of the definition for "Participant selection bias"

Participant selection bias is A selection bias …

A selection bias that results from differential selection of participants so that the resulting sample is no longer representative of the source population-**Harold Lehmann**

which affects the recruitment process

selection bias that affects the recruitment process of study participants in a clinical trial

"Participants in research may differ systematically from the population of interest. For example, participants included in an influenza vaccine trial may be healthy young adults, whereas those who are most likely to receive the intervention in practice may be elderly and have many comorbidities, and are therefore not representative. Similarly, in observational studies, conclusions from the research population may not apply to real-world people, as the observed effect may be exaggerated or it is not possible to assume an effect in those not included in the study.Selection bias can arise in studies because groups of participants may differ in ways other than the interventions or exposures under investigation. When this is the case, the results of the study are biased by confounding".-**Catalog of Bias**

"Bias in selection of participants into the study"-**ROBINS-I**

"Could the selection of patients have introduced bias?" **Quadas 2**

A selection bias where key characteristics of the participants differ systematically from the population of interest.-**Harold Lehmann**

The definition should represent both Observational vs Interventional (RCT)studies

we need to consider selection of sampling frame vs selection of the sample

A selection bias that occurs when the sampling frame is not representative of the population of interest.

We narrowed the possibilities to the following two choices:

Participant selection bias is...

1) A selection bias where key characteristics of the participants differ systematically from the population of interest.

2) A selection bias that results from differential selection of participants where the resulting sample is no longer representative of the source population

We decided that the first choice, highlighted in yellow above should be the definition sent out on the next ballot for the expert working group as the draft definition of "participant selection bias".

Participant selection bias= A selection bias where key characteristics of the participants differ systematically from the population of interest.

February 26, 2021

The Risk of Bias Terminology and Tooling Working Group reviewed the votes for the first term (Bias) and it was approved unanimously with 8 people voting. We discussed structural changes needed to prepare for subsequent steps with the Code System Robot Template. We did not start a new term but this was a necessary initial factor for the system we are developing. We can revisit the concepts for the terms in the Research Design Working Group meeting on Tuesday.

February 19, 2021

The group worked to create a code system robot template spreadsheet (link included below)

https://docs.google.com/spreadsheets/d/1t2MKcQjlrCGrB7gwPIL6J8fTL62oB7ck/edit#gid=451898244

Although our initial goal was to map two specific risk of bias terms (inappropriate selection criteria and participant selection bias) as a proof of concept as we try to develop a new system for our risk of bias code system, we soon realized that we needed to start with the main concepts first (the trunk instead of the leaves).

We discussed at length where the concept of bias fits into the Basic Formal Ontology and landed at least temporarily with the concept of quality (BFO -0000019) which also includes the concept of color.

This is a very abstract concept to map. Another placeholder to consider is “process” this may be used when considering the ROB assessment which is another concept that will require mapping.

We also discussed the concept of bias as false certainty and decided to use bias as our main term with false certainty as an alternative term.

We then sought to create a definition for the overall concept of bias. We approached this in the same way we approached other term definitions and consulted the risk of bias tools used in earlier mapping (such as ROBIS, QUIPS, PROBAST, etc.) and also considered definitions from Merriam Webster and New Oxford Dictionary. The group agreed on the following definition:

Bias Definition-A systematic distortion in research results (estimation of effect, association, or inference)

Once this decision was made the group decided to involve the expert working group. Joanne will create a simple google form ballot to be sent to the expert working group(EWG) to vote on the above “high level” definition of bias. This will allow us to test and refine our voting system which will be used for all of the other terms as we finalize their placement and definition in our code system. Subsequent votes will likely be done with “batches” of related ROB terms.

A first draft of the ballot can be found here:

https://docs.google.com/forms/d/1koXT1O7FDtktV4t0A2lzdEbVa9ZDNoZ6lIWZYiH00yo

Feb 12, 2021

The Risk of Bias Terminology and Tooling Working Group revised the Risk of Bias and Safeguard Code System 2021 Feb 12 by reviewing more Safeguard Items. In the process 3 Risk of Bias terms were added or majorly revised:

- **Inappropriate data source for participant selection**
- **Inappropriate time interval between predictor and outcome**
- **Inconsistency within sensitivity analyses**

February 5, 2021

We introduced the new Risk of Bias Terminology and Tooling Working Group today –The group added Safeguard Items to the Risk of Bias Concept List. We discovered that we could utilize the original phrasing which we have already captured in step 3 code system mapping. See the url below for details.

https://docs.google.com/document/d/1IHlkbldx2ubtvId9MHiWgWbRJe07rXVg

Review of the Risk of Bias of Systematic Reviews Survey Tool developed for the Systematic Meta-Review project was tabled until the next meeting.

Jan 22, 2021

The Risk of Bias Code System Development Steering Group accepted all the suggested changes in the Risk of Bias Code System TABLE FORM and adjusted the citations. This now appears stable to use as the key results for an introductory article 'Making Science Computable: An expanded catalog of bias to inform critical appraisal'

Jan 15, 2021

We discussed the concept of describing each of the risk of bias items using causal diagrams or directed acyclic graphs or DAGs. We discussed two articles for explanation of the diagram concept (urls below). We looked at a diagram created by MA which can be observed here. We would like to add the property "study design" and include it in our concept map. This would help to limit which concepts should be used for a study design.

https://cjasn.asnjournals.org/content/12/3/546#sec-3

https://research.vu.nl/en/publications/assessing-risk-of-bias-a-proposal-for-a-unified-framework-for-obs

It was suggested that we use Basic Formal Ontology to organize our ROB code system. Vignesh will present information on this topic at the next meeting.

Jan 8, 2021

The group accepted the most recent changes in the Risk of Bias code system (Table Form) and discussed how close we are to having a publishable version of this code system. We decided that it would be best to publish now at this level of development instead of waiting to get through all 13 steps. Brian has been in contact with publishers for both JAMA and BMJ to gauge interest. BMJ immediately expressed interest. Bhagvan will look at choice of question bias to see if it is in any of the existing ROB tools.

Jan 5, 2020

We worked on the Risk of Bias code system during the Study Design code system meeting time today. The latest version of the risk of bias code system can be found here. Major changes involved and discussion involved the distinction between selective analysis bias and selective reporting bias.

Dec 18, 2020

We discussed final additions to the Risk of Bias Code systems tables. We agreed that we could use a journal article as a reference for a few of the concepts that were not actually found in our mapping but that were suggested by the expert working group. We also added lead-time bias as a new concept. We will now commence with writing the "prose" of the paper about our Risk of Bias Code System.

December 11, 2020

The group discussed an upcoming publication of the Risk of Bias code system compiled by the COVID-19 Knowledge Accelerator. We contemplated the layout (Outline vs Table) format for the results section of the paper and started with the creation of a table that encompasses the content of the code system. We felt that the entire code system could be included within the results without placing it in an appendix or supplement.

December 4, 2020

The Risk of Bias group today worked to organize the additional codes added from the Catalog of Bias. Most of the discussion was within the heading of detection bias. The resulting "simplified" list of risk of detection bias concepts can be seen here.

November 2020 Progress reports

November 20, 2020

We started to map the "Catalog of Bias" to our code system. This ontology is extensive and will require a larger effort than previous ontologies we have consulted for Risk of Bias. After assessing 8 terms, we added 7 new terms to our list. We will resume starting with letter C in the alphabetical list. No decision was made regarding the cancellation of this meeting next week for the celebration of Thanksgiving in the United States.

November 13, 2020

Agenda item-check for and or add survivorship bias or survivor effect to list of risk of bias codes.

move 6a3. Inadequate Intention-To-Treat Analysis to category of 6e. Analysis Selection Bias

Consider further subcategory of 6e5. Analysis Inclusion Bias to contain:

6e5a. Subgroup analysis

6e5b. Inadequate Intention-To-Treat Analysis

6e5c. Survivorship bias

November 6, 2020

We considered the concept of multiple comparison adjustment corrections of p value due to multiple testing. It was argued that in frequentist analysis this is an important thing to add to our master list of bias concepts. Therefore, we added two new terms to our Risk of Bias template:

Item 6e6-"Analysis Threshold Selection Bias"

Item 6e6a "Absence of Multiple Comparison Adjustment"

These changes had unanimous agreement from the group attending the meeting.

We then went back through the ontologies that we had already mapped (EDDA, OBCS, Stato, and NCI Thesaurus) to map these concepts.

We agreed not to add the concept of "background instrument noise" as a specific type of measurement bias in the interest of keeping the list of terms efficient, this was more detail than needed.

We then started mapping the next ontology, "OCRe", chosen because it is also in the BioPortal tool which makes the terms easier to map.

Archived Risk of Bias Progress Reports prior to November 2020

Progress Report

This active work group for the COVID-19 Knowledge Accelerator project will:

1) Define use cases for standard electronic expression of assessments of quality or certainty regarding evidence at both the level of study results and bodies of evidence.

2) Define processes for expression of quality and certainty ratings, including human and machine efforts.

3) Demonstrate application of the processes and iteratively refine the processes.

4) Introduce the processes to others, evaluate feedback, and iteratively refine.

July 3, 2020

We discussed examples of goals from 3 other Process Development Work Groups and reviewed actual FHIR Resource examples to understand the handling of risk of bias and certainty of evidence assessments so far. Next week we will continue to determine the specific goals for this Work Group.

Examples from other work groups:

A) **Classifying Content Process Development Work Group**

1. Define a set of concepts to use for classification.
    a. Concepts to use for classification may include what the article is about, types of information (such as guideline), study design (such as RCT), detailed descriptions of evidence variables (commonly considered as PICO elements), and other classifiers as the needs become more apparent.
2. Map out classification efforts done by others (human and/or machine).
3. Define processes for classification of COVID-19 related articles, including re-use of classification efforts by others.
4. Demonstrate application of the processes to the classification of COVID-19 related articles.
5. Refine processes (based on learned results from the demonstration)
6. Introduce the processes and/or the results to others.
7. Evaluate feedback from others to refine the processes.
8. Maintain a consensus-based dialog for defining and refining the processes.

A) **Statistical Content Process Development Work Group**

The objectives for this group are:

1) Identify “problems to solve” by recognizing an attempted or desired use of the FHIR Statistic Datatype that is not well supported.

2) Define use cases for the FHIR Evidence Resource related to the expression of evidence results within the Statistic Datatype.

3) Identify and define common statistical concepts, methods, expectations, standards and expressions for these use cases.

4) Define processes for expression of statistical data, including human and machine efforts.

5) Demonstrate application of the processes and iteratively refine the processes.

6) Introduce the processes to others, evaluate feedback, and iteratively refine.

Processes can be:

- **Best practices, guidelines, standards produced by others**
- **Expectations for how to interpret data**
- **Expectations for what data gets entered in what element in what form**
- **Workflow expectations**

A) **Summarization Process Development Work Group**

This active work group for the COVID-19 Knowledge Accelerator project will:

1) Define use cases for the FHIR EvidenceReport Resource related to the summarization of evidence results.

2) Identify and define common styles and expectations for these use cases.

3) Define processes for summarization, including human and machine efforts.

4) Demonstrate application of the processes and iteratively refine the processes.

5) Introduce the processes to others, evaluate feedback, and iteratively refine.

July 10, 2020

We reviewed and discussed upcoming expectations for reviewing and managing value sets related to certainty of evidence and risk of bias assessments. This PDWG could also be the key liaison with the GRADE Working Group.

July 17, 2020

We reviewed the application so far of risk of bias classifiers at the study level and certainty of evidence ratings at the evidence level. We discussed concepts of equity (such as diversity of population included) and how it is important and included in evidence production and evidence-to-recommendation framework developments but not clearly commonly used in evidence reporting for study results and summary of findings of a body of evidence.

We also reviewed the Evidence Ecosystem image set and noted it will be important to show an overlay at each step that starts with “What is important?” and “Important to whom?”

July 24, 2020

We reviewed the Project Coordination Work Group discussion on Vocabulary management including the specific ask for this work group:

Rating Certainty/Quality PDWG: Ask this group to focus on the "terminology/vocabulary management process" efforts related to Evidence.certainty element (including coordination with GRADE Working Group) and RiskOfBias Assessment classifiers found at http://build.fhir.org/valueset-evidence-classifier-code.html, and to identify a WG Terminology Facilitator.

Jennifer reports that a Cochrane group signaled interest in making sure it is done right when considering applying Risk Of Bias 2 (ROB2) concepts to implementation within DistillerSR. This is a good signal of interest where specifying the standard codes for reporting these concepts in an interoperable way is getting this work done with Cochrane (subject matter experts in what should be coded) and DistillerSR (implementer that will process the coded data)

Our goal is not to reach agreement on the ROB tool to use. Our goal is to reach agreement on a standard set of terms to convey ROB concepts regardless of which tool is used. For example:

Jadad criteria may include:

- randomization A
- blinding B
- withdrawals and dropout C

ROB1 may include:

- randomization sequence generation D
- allocation concealment E
- blinding of participants and personnel B1
- blinding of outcome assessment B2
- incomplete outcome data C
- selective outcome reporting F
- other bias

ROB2

- ….

A-F and B1, B2 codes above show how these concepts might be considered same, different, or related (parent-child) in reaching a common code set.

Jennifer will reach out to Julian Higgins and Johnathan of Cochrane ROB2 focus to join this group.

July 31, 2020

Meeting canceled due to low participation.

August 7, 2020

EPCs also use ROB tools for non-randomized studies such as ROBINS-I and Newcastle-Ottawa. We should create a code set for risk of bias classifiers that includes these concepts as well.

To get started on this ROB classifier code set we will start with the following ROB tools:

- ROB1 for RCTs
- ROB2 for RCTs
- ROBINS-I
- Newcastle-Ottawa
- ROBIS (ROB for systematic reviews)

As we started to create a spreadsheet for this mapping we explored more deeply the need for a subcomponent/type/rating model instead of ROB yes/no classifiers and determined the best fit is to extend Evidence.certainty to handle risk of bias communication for individual study/outcome evidence.

We will need to consider 3 code sets used in Evidence.certainty to meet the needs across risk of bias assessments.

August 14, 2020

To model risk of bias assessment in the Evidence.certainty schema there are 3 possible patterns:

A) Evidence.certainty.rating = the overall risk of bias for the study estimate, Evidence.certainty.certaintySubcomponent = assessment of risk of bias factors
B) Evidence.certainty.certaintySubcomponent = used for both overall and for factors; .type=RoB when rating is the overall risk of bias, .type='factor' when rating is the risk of bias factor
C) Evidence.certainty.certaintySubcomponent = the overall risk of bias for the study estimate (.type = RoB), Evidence.certainty.certaintySubcomponent.certaintySubcomponent = assessment of risk of bias factors

A) existing 2-level hierarchy
B) flattened within subcomponent - no structured hierarchy
C) nested 3-level hierarchy

A1) code system for Evidence.certainty.rating includes both the rating and the type (CoE or RoB)

A2) add Evidence.certainty.type to cover type (CoE or RoB) separately from Evidence.certainty.rating

Another 'benefit' of A2 is that one could use multiple instances of Evidence.certainty to represent certainty ratings by multiple different people or groups and use the Evidence.certainty.type to represent the different people or groups.

C) nested hierarchy is considered optimal choice and RoB codes will then only need to be applied to the subcomponent.type and subcomponent.rating value sets.

August 21, 2020

To adapt for this approach the only change to the Evidence.certainty element would be to add:

Evidence.certainty.certaintySubcomponent.subcomponent 0..* “see Evidence.certainty.certaintySubcomponent for Datatype”

The following value sets would be used throughout the nested elements:

type	0..*	CodeableConcept	Aspect of quality or certainty being rated CertaintySubcomponentType (Extensible)
rating	0..*	CodeableConcept	Quality or certainty of the aspect CertaintySubcomponentRating (Extensible)

Risk of Bias code set spreadsheet updated with mapping of ROB1 and ROB2 tools. The current draft candidates for ROB “codes” for the CertaintySubcomponentType value set are:

Comparative Selection Bias

- Comparator Selection Bias - Random sequence generation
- Comparator Selection Bias - Allocation concealment
- Comparator Selection Bias - Baseline differences

Performance Bias

- Performance Bias - Blinding of Participants
- Performance Bias - Blinding of Intervention Deliverers
- Performance Bias - Deviations from intended Intervention
- Performance Bias - Imbalance in Deviations from Intended Interventions

Performance Adherence Bias

- Performance Adherence Bias - Blinding of Participants
- Performance Adherence Bias - Blinding of Intervention Deliverers
- Performance Adherence Bias - Imbalance in Deviations from intended Intervention
- Performance Adherence Bias - Nonadherence of Implementation
- Performance Adherence Bias - Nonadherence of Participants

Attrition Bias

- Attrition Bias - Incomplete Outcome Data
- Attrition Bias - Influence of Incomplete Outcome Data
- Attrition Bias - Influence of Outcome on Missingness of Data

Detection Bias

- Detection Bias - Appropriateness of Measurement Method
- Detection Bias - Imbalance in Measurement Method
- Detection Bias - Blinding of Outcome Assessors
- Detection Bias - Influence of Blinding of Outcome Assessors

Reporting Bias

- Reporting Bias - Pre-Specified Analysis Plan
- Reporting Bias - Selective outcome measure reporting (within outcome domain)
- Reporting Bias - Selective outcome measure reporting (across outcome domains)

Analysis Bias

- Analysis Bias - Intention-To-Treat Analysis
- Analysis Bias - Adherence Effect Analysis
- Analysis Bias - Selective analysis reporting (from repeated analyses at multiple times)
- Analysis Bias - Selective analysis reporting (from multiple analytic models)

August 28, 2020

Consider a rating of ROB _Some concerns_ due to ROB2 **Risk of bias arising from the randomization process** rated as _Some concerns__ due to **1.1 Was the allocation sequence random?** was rated as __No__

this may look like:

Evidence.certainty

certaintySubcomponent

type = RiskOfBias

rating = SomeConcerns

subcomponent

type = ComparatorSelectionBias

rating = SomeConcerns

subcomponent

type = “Comparator Selection Bias - Random sequence generation”

rating = NoRandomAllocationSequence

We modified the Risk of Bias code set spreadsheet to add a tab for rating codes in addition to type codes.

We would like to write up a prospective methodology (protocol) to create 4 code systems (Statistic Type Code System, Statistic Model Code System, Study Design Code System, Risk Of Bias Code System) that will be functional for computable expression of scientific knowledge with open global interoperability.

Perhaps a good start is:

1. Assemble an expert working group for each code system.
2. Identify sources to signal a common need for codes in the code system. Sources to signal a need are tools or systems in common current use for reporting these concepts.
3. Create a list of non-redundant concepts that can convey the concepts in commonly used tools and systems.
4. Identify ontologies that are likely to include concepts on the list and are available for use without restrictions.
5. For each concept extract the display, synonym list, and the definition from each ontology that best matches. Note if there are close but not exact matches.
6. For each concept:
    a. Review the displays, synonyms lists, and definitions from available ontologies
    b. Draft a preferred display, synonym list, and definition.
7. Each member of the expert working group will note agreement with the display, synonym list and definition for each concept or suggest changes. This is the key contribution for authorship if not actively contributing to steps 1-6. This process will be online and asynchronous.
8. Review suggested changes in open meetings. Repeat step 7 for items that are changed.
9. If a concept does not achieve universal agreement (a set of display, synonym list and definition entries without complete agreement) each person who recommended a change will write a rationale. The rationales for the variant approaches will be shared with the expert working group before a group meeting. The group meeting will discuss and if unable to reach consensus will proceed with a version that achieves at least 80% agreement with at least 5 people voting. (TBD if voting in meeting or online in defined time period, eg 24 hours after the meeting)

September 4, 2020

In response to other groups seeking support for making computable expressions for Recommendations like we have done for Evidence, we drafted a Recommendation Resource. Here is the message sent to others about it:

The format for human expression can look very different from the format for computable expression. But if we can agree to a standard for computable expression we can support a near-infinite set of patterns of human expression.

Some thoughts below to inform a computable expression of a "Recommendation" and I end with a link to a first draft for it.

As a recap to some of the concepts to clarify recommendation vs. CDS artifact:

One of the challenges in defining L2/L3 and recommendation/CDS may be recognized by 2 different factors (Recommendation/Decision Rule, Digital/Computable):

- A Recommendation can be an expression of what should be done – Flu vaccine is recommended for people who have not received a flu vaccine this season.
- A Decision Rule can be an expression of the logic to be applied – If a person does not have a record of receiving a flu vaccine this season, then offer/provide a flu vaccine.

- The Recommendation and Decision Rule can be applied in clinical practice completely using Print expressions.
- The Recommendation and Decision Rule can be applied in clinical practice completely using Digital expressions. This sentence is shared with you now in a Digital expression in this email but is not a Computable expression of the concepts.
- The Recommendation can be converted to a Computable expression – an L3 artifact that provides "Flu vaccine" as a codeable concept, "people who have not received a flu vaccine this season" as a codeable concept, and "is recommended for" as a codeable concept. This L3 artifact can be considered a CDS artifact but it is not yet sufficient for immediate functional use in a specific CDS system.
- The Decision Rule can be converted to a Computable expression – in addition to the codeable concepts in the Recommendation, additional codeable concepts to express include "have a record of", "offer/provide", and the "if…then" logic. This L3 artifact would also be considered a CDS artifact.

The original goal of the EBMonFHIR project was to provide for computable expressions of evidence and recommendations. With the CDC ACQ Informatics Value Stream effort focused on converting guidelines to CDS artifacts, a companion CPGonFHIR project developed. It appears the CPGonFHIR expresses Decision Rules in computable form and the PlanDefinition Resource expresses the action(s) in computable form. We have been discussing shared use of Group and EvidenceVariable Resources that can express parts of the "when

recommended" concepts in computable form. However, there is not yet a specific resource for the Recommendation in computable form which can be used prior to creating the Decision Rule derived from that Recommendation.

Working off of what we have learned from the evidence-related Resources and the PlanDefinition Resource, I have created a first draft of a Recommendation Resource to bridge this gap.

September 11, 2020

We discussed how equity concerns (including improper interpretations of confounding variables) can be an important component of Risk Of Bias assessment for evidence interpretation. Some other equity concerns (including limited representation of diverse populations) may also be an important component of Indirectness assessment for evidence interpretation. It is more complex than simply routing the overall area as a singular concept.

Working through our 13-step process for Risk Of Bias Code System Development:

1. Assemble an expert working group -- will add Society for Participatory Medicine and PCORI to the invite list. (Danny can help share with these 2 groups)
2. Identify common tools and systems for evaluating and reporting Risk Of Bias - added QUIPS, QUADAS and PROBAST

September 18, 2020

We reviewed the current state of the Risk of Bias Code System Development.

For Step 1. Assemble an expert working group:

- The Code System Development Protocol is near-complete and awaiting sign-off by all authors.
- The Invitation to Join Expert Working Group is ready and will be sent widely starting Monday.
- If you have not signed up yet, please complete the Code System Development Intake Form.

For Step 2. Identify commonly used tools and systems the codes system should support, we have identified:

- ROB-1
- ROB-2
- ROBINS-I
- Newcastle-Ottawa
- ROBIS
- COKA ROB classifiers used with early COVID-19 articles
- QUIPS
- PROBAST
- QUADAS-2

Any others to add?

ROB-1, ROB-2 and COKA items have been added to the Risk Of Bias Code System Step 3 spreadsheet.

Who will add the data for….?:

- ROBINS-I -- Brian and Joanne started.
- Newcastle-Ottawa
- ROBIS
- QUIPS

- PROBAST
- QUADAS-2

Joanne also identified catalogofbias.org which may serve as a comprehensive listing for this code system.

September 25, 2020

So far 41 people from 21 countries have signed up for an Expert Working Group for one of our code systems, of whom 23 people signed up for the Risk of Bias Code System Expert Working Group.

The group reviewed the mappings of ROB1, ROB2 and ROBINS-I to the Risk Of Bias Code System Step 3 spreadsheet. Next steps are to list the concepts from the other rating tools to support mapping those. We created separate tabs to the spreadsheet for ROBIS, Newcastle-Ottawa (cohort studies) and Newcastle-Ottawa (case-control studies). We will list these concepts before our next Steering Group meeting so we can map or review the mapping at the next group meeting. If you would like to help with listing those concepts (or help map QUIPS, PROBAST or QUADAS-2) please contact balper@computablepublishing.com or krobin@jhmi.edu for an orientation to the effort.

October 2, 2020

The ROBIS tools was mapped to the Risk Of Bias Code System Step 3 spreadsheet so the current list of 106 risk of bias codable concepts (still pending 4 more tools to add) are:

Types of Risk of Bias

A. Comparator Selection Bias
    A1. Comparator Selection Bias - Random sequence generation
    A2. Comparator Selection Bias - Allocation concealment
    A3. Comparator Selection Bias - Baseline differences
    A4. Potential for Confounding
    A5. Confounding by follow-up time
    A6. Prognostic factors influencing intervention
    A7. Post-intervention confounding
B. Participant Selection Bias
    B1. Post-intervention factors bias selection
    B2. Intervention associated with post-intervention factors that bias selection
    B3. Outcome associated with post-intervention factors that bias selection
    B4. Mismatch in start of intervention and start of follow-up
C. Classification Bias
    C1. Intervention definition unclear
    C2. Intervention definition not recorded at start of intervention
    C3. Intervention classification potentially influenced by risk of outcome
D. Performance Bias
    D1. Performance Bias - Blinding of Participants
    D2. Performance Bias - Blinding of Intervention Deliverers
    D3. Performance Bias - Deviations from intended Intervention
    D4. Performance Bias - Imbalance in Deviations from Intended Interventions
E. Performance Adherence Bias
    E1. Performance Adherence Bias - Blinding of Participants
    E2. Performance Adherence Bias - Blinding of Intervention Deliverers

- E3. Performance Adherence Bias - Imbalance in Deviations from intended Intervention
- E4. Performance Adherence Bias - Nonadherence of Implementation
- E5. Performance Adherence Bias - Nonadherence of Participants

F. Attrition Bias

- F1. Attrition Bias - Incomplete Outcome Data
- F2. Attrition Bias - Influence of Incomplete Outcome Data
- F3. Attrition Bias - Influence of Outcome on Missingness of Data
- F4. Exclusions due to missing data on intervention
- F5. Exclusions due to missing data on measured variables
- F6. Imbalance in missing data
- F7. Sensitivity to missing data

G. Detection Bias

- G1. Detection Bias - Appropriateness of Measurement Method
- G2. Detection Bias - Imbalance in Measurement Method
- G3. Detection Bias - Blinding of Outcome Assessors
- G4. Detection Bias - Influence of Blinding of Outcome Assessors
- G5. Detection Bias - systematic errors in outcome measurement
- G6. Bias in measurement of confounders
- G7. Error in data collection not minimized
- G8. Insufficient study characteristics available for proper results interpretation
- G9. Incomplete collection of relevant study results for synthesis
- G10. Methodologic quality assessment inadequate
- G11. Error in risk of bias assessment not minimized

H. Analysis Bias

- H1. Bias controlling for confounding factors
- H2. Bias controlling for confounding factors and time-varying confounding
- H3. Adjustment for selection bias
- H4. Analysis Bias - Intention-To-Treat Analysis
- H5. Analysis Bias - Adherence Effect Analysis
- H6. Analysis Bias - Selective analysis reporting (from repeated analyses at multiple times)
- H7. Analysis Bias - Selective analysis reporting (from multiple analytic models)
- H8. Analysis Bias - Early trial termination
- H9. Analysis Bias - Preliminary analysis
- H10. Analysis bias - Subgroup analysis

I. Reporting Bias

- I1. Reporting Bias - Pre-Specified Analysis Plan
- I2. Reporting Bias - Selective outcome measure reporting (within outcome domain)
- I3. Reporting Bias - Selective outcome measure reporting (across outcome domains)
- I4. Reporting Bias - pre-final publication form
- I5. Reporting bias - Subgroup analysis
- I6. Reporting bias - Interpretation of findings not addressing risk of bias
- I7. Reporting bias - Relevance of studies to research question not appropriately considered
- I8. Reporting bias - Results emphasized based on statistical significance

J. Study Selection Bias

- J1. Study eligibility criteria not prespecified
- J2. Study eligibility criteria not adhered to
- J3. Study eligibility criteria not appropriate for review question
- J4. Study eligibility criteria ambiguous
- J5. Study eligibility criteria limits for study characteristics not appropriate

J6. Study eligibility criteria limits for information sources not appropriate
J7. Database search sources not appropriate
J8. Nondatabase search sources inadequate
J9. Search strategy not sensitive
J10. Search strategy limits for information sources not appropriate
J11. Error in study selection not minimized

K. Synthesis Bias
K1. Synthesis missing eligible studies
K2. Study parameters not appropriate for synthesis
K3. Heterogeneity not addressed
K4. Sensitivity to factors
K5. Biases in studies influence synthesis

Ratings for Risk of Bias

R. Rating of Certainty (category, not a codable concept)
R1. Low Risk Of False Certainty
R2. Moderate Risk of False Certainty
R3. High Risk Of False Certainty
R4. Serious Risk of False Certainty
R5. Critical Risk of False Certainty
R6. Some Risk of False Certainty

S. Rating of Factor Presence (category, not a codable concept)
S1. Factor Present
S2. Factor Likely Present
S3. Factor Likely Absent
S4. Factor Absent
S5. No Information

T. Rating of Bias Direction (category, not a codable concept)
T1. Risk Of Bias Favoring Experimental
T2. Risk Of Bias Favoring Comparator
T3. Risk Of Bias Towards Null
T4. Risk Of Bias Away From Null
T5. Risk Of Bias Direction Unpredictable

U. Rating of Influence (category, not a codable concept)
U1. Factor has potential to impact results
U2. Factor likely has potential to impact results
U3. Factor likely does not have potential to impact results
U4. Factor does not have potential to impact results

October 9-10, 2020

The remaining ROB tools were mapped to the Risk Of Bias Code System Step 3 spreadsheet and substantial reorganization applied to prepare for a Concept List for Risk of Bias Code System Version 1.0.0, to include in the draft manuscript Making Science Computable: Developing Code Systems for Statistics, Study Design and Risk of Bias to be submitted October 15.

This list has 170 non-redundant codable concepts for the Risk of Bias Code System (items bolded if they are both a classifier and a codable concept):

Type Classifiers

1. **Participant Selection Bias** (for overall sample, not for comparator group)
    - 1a. Inappropriate selection criteria
    - 1b. Biased sampling strategy
    - 1c. Non-representative sample
    - 1d. Inadequate participation by eligible persons
    - 1e. Post-intervention factors bias selection
    - 1f. Intervention associated with post-intervention factors that bias selection
    - 1g. Outcome associated with post-intervention factors that bias selection
    - 1h. Mismatch in start of intervention and start of follow-up
2. **Comparator Selection Bias**
    - 2a. Inadequate Random sequence generation
    - 2b. Inadequate Allocation concealment
    - 2c. Biased selection of the non exposed cohort
    - 2d. **Case-control design**
        - 2d1. Case-control design without appropriate definition of controls
        - 2d2. Case-control design without appropriate selection of controls
        - 2d3. Case-control design without description of selection of controls
        - 2d4. Case-control design with factor-specific concern for comparability of cases and controls
    - 2e. **Potential for Confounding**
        - 2e1. Baseline differences
        - 2e2. Confounding by follow-up time
        - 2e3. Prognostic factors influencing intervention
        - 2e4. Post-intervention confounding
3. **Performance Bias**
    - 3a. Performance Bias - Blinding of Participants
    - 3b. Performance Bias - Blinding of Intervention Deliverers
    - 3c. Performance Bias - Deviations from intended Intervention
    - 3d. Performance Bias - Imbalance in Deviations from Intended Interventions
    - 3e. **Performance Adherence Bias**
        - 3e1. Performance Adherence Bias - Blinding of Participants
        - 3e2. Performance Adherence Bias - Blinding of Intervention Deliverers
        - 3e3. Performance Adherence Bias - Imbalance in Deviations from intended Intervention
        - 3e4. Performance Adherence Bias - Nonadherence of Implementation
        - 3e5. Performance Adherence Bias - Nonadherence of Participants
4. **Attrition Bias**
    - 4a. Incomplete Outcome Data
    - 4b. Influence of Incomplete Outcome Data
    - 4c. Influence of Outcome on Missingness of Data
    - 4d. Exclusions due to missing data on intervention
    - 4e. Exclusions due to missing data on measured variables
    - 4f. Imbalance in missing data
    - 4g. Sensitivity to missing data
    - 4h. Inadequate response rate
    - 4i. Inadequate understanding of missing data

5. **Detection Bias**

5a. **Detection Bias for Outcomes**

5b. **Detection Bias for Exposures**

5c. **Detection Bias for Reference Standard**

5d. **Detection Bias for Index Test**

5e. **Detection Bias for Classifiers**

5f. **Detection Bias for Confounders**

5g. Insufficient study characteristics available for proper results interpretation

5h. Incomplete collection of relevant study results for synthesis

5i. Methodologic quality assessment inadequate

5j. Error in risk of bias assessment not minimized

5x1. **Detection Bias for X - Classification Bias** (for x=X, substitute a=Outcomes, b=Exposures, c=Reference Standard, d=Index Test, e=Classifiers, or f=Confounders)

5x1a. Nonrepresentative definition

5x1b. Risk of misclassification

5x1c. Definition not prespecified

5x1d. Threshold not prespecified

5x1e. Classification potentially influenced by risk of outcome

5x1f. Definition unclear

5x2. **Detection Bias for X - Assessment Method** (for x=X, substitute a=Outcomes, b=Exposures, c=Reference Standard, d=Index Test, e=Classifiers, or f=Confounders)

5x2a. Inappropriate Measurement Method

5x2b. Improper conduct of measurement assessment

5x2c. Incomplete application of measurement assessment

5x2d. Inadequate follow up period for outcome of interest

5x2e. Assessment method unclear

5x2f. Error in data collection not minimized

5x3. **Detection Bias for X - Imbalance** (for x=X, substitute a=Outcomes, b=Exposures, c=Reference Standard, d=Index Test, e=Classifiers, or f=Confounders)

5x3a. Imbalance in Application of Measurement Method

5x3b. Differential data availability during tests

5x3c. Inappropriate delay between index test and reference standard

5x4. **Detection Bias for X - Confounding Influence** (for x=X, substitute a=Outcomes, b=Exposures, c=Reference Standard, d=Index Test, e=Classifiers, or f=Confounders)

5x4a. Incorporation bias (eg non-independence of reference standard and index test)

5x4b. Lack of blinding (eg blinding of index test result during reference test, blinding of outcome assessors)

5x4c. Influence of Blinding on Measurement

6. **Analysis Bias**

6a. **Bias controlling for confounding factors**

6a1. Bias controlling for confounding factors and time-varying confounding

6a2. Adjustment for selection bias

6a3. Inadequate Intention-To-Treat Analysis

6a4. Inadequate Adherence Effect Analysis

6a5. Predictors included in outcome definition

6b. Analysis Model Selection Bias - improper statistical model

6c. Inadequate numbers for analysis

6d. **Bias in Handling of Data**

6d1. Incomplete data analysis
6d2. No accounting for uninterpretable results
6d3. Inappropriate handling of missing data
6d4. Inappropriate handling of variables
6d5. Inappropriate handling of complexities in the data
6d6. Differential handling of confounder measurement
6d7. Handling of confounders unclear
6d8. Inappropriate handling of missing confounder data

6e. **Analysis Selection Bias**

6e1. Selective analysis reporting (from repeated analyses at multiple times)
6e2. Selective analysis reporting (from multiple analytic models)
6e3. Early trial termination
6e4. Preliminary analysis
6e5. Subgroup analysis

6f. **Analysis bias in predictive model development**

6f1. Selection of predictors based on univariable analysis
6f2. Inappropriate evaluation of model performance measures
6f3. Model overfitting and optimism
6f4. Final model not corresponding to multivariable analysis

7. **Reporting Bias**

7a. Reported Result Not Following Pre-Specified Analysis Plan
7b. inadequate reporting to assess analytic strategy
7c. Selective outcome measure reporting (within outcome domain)
7d. Selective outcome measure reporting (across outcome domains)
7e. Pre-final publication form
7f. Subgroup analysis (reporting bias)
7g. No explanation of withdrawals
7h. Interpretation of findings not addressing risk of bias
7i. Relevance of studies to research question not appropriately considered
7j. Results emphasized based on statistical significance

8. **Study Selection Bias**

8a. **Bias in study eligibility criteria**

8a1. Study eligibility criteria not prespecified
8a2. Study eligibility criteria not appropriate for review question
8a3. Study eligibility criteria ambiguous
8a4. Study eligibility criteria limits for study characteristics not appropriate
8a5. Study eligibility criteria limits for information sources not appropriate

8b. Database search sources not appropriate
8c. Nondatabase search sources inadequate
8d. Search strategy not sensitive
8e. Search strategy limits for information sources not appropriate
8f. Study eligibility criteria not adhered to
8g. Error in study selection not minimized

9. **Synthesis Bias**

9a. Synthesis missing eligible studies
9b. Study parameters not appropriate for synthesis
9c. Heterogeneity not addressed
9d. Sensitivity to factors
9e. Biases in studies influence synthesis

L. Qualitative Research (CATEGORY ONLY)

L1. Inappropriate qualitative approach
L2. Inadequate qualitative data collection methods
L3. Inappropriate qualitative analysis
L4. Unsubstantiated interpretation of results
L5. Incoherence between data, analysis and interpretation

M. Mixed Methods Research (CATEGORY ONLY)
M1. Inadequate rationale for mixed methods design
M2. Ineffective integration of study components
M3. Inappropriate interpretation of integration of qualitative and quantitative findings
M4. Inadequate handling of inconsistency

N. Predictive Model Subset (CATEGORY ONLY)
N1. **Bias in Predictive Model Development** (used to subset classifiers noted elsewhere to be specific to predictive model development)
N2. **Bias in Predictive Model Validation** (used to subset classifiers noted elsewhere to be specific to predictive model validation)
N3. Absence of any validation
N4. Absence of any external validation

<u>Rating Classifiers</u>

R. Rating of certainty (CATEGORY ONLY)
R1. Low Risk Of False Certainty
R2. Moderate Risk of False Certainty
R3. High Risk Of False Certainty
R4. Serious Risk of False Certainty
R5. Critical Risk of False Certainty
R6. Some Risk of False Certainty

S. Rating of factor presence (CATEGORY ONLY)
S1. Factor Present
S2. Factor Likely Present
S3. Factor Likely Absent
S4. Factor Absent
S5. No Information
S6. Factor Presence or Absence Unclear

T. Rating of bias direction (CATEGORY ONLY)
T1. Risk Of Bias Favoring Experimental
T2. Risk Of Bias Favoring Comparator
T3. Risk Of Bias Towards Null
T4. Risk Of Bias Away From Null
T5. Risk Of Bias Direction Unpredictable

U. Rating of influence (CATEGORY ONLY)
U1. Factor has potential to impact results
U2. Factor likely has potential to impact results
U3. Factor likely does not have potential to impact results
U4. Factor does not have potential to impact results

October 16, 2020

Step 3 Risk of Bias Code System now has 170 draft terms.

Step 4 Ontology Identification now has 22 ontologies eligible for mapping.

Step 5 initial demonstration used the EDDA Study Design Taxonomy and was completed for Step 5 EDDA Ontology Mapping.

We created Step 5 TEMPLATE Ontology Mapping to support making a new working spreadsheet for each ontology to be mapped.

We then created Step 5 OBCS Ontology Mapping for the next ontology to map.

October 23, 2020

We updated the Step 5 TEMPLATE Ontology Mapping to adapt to recent Step 3 results changed across the 4 code systems, then created Step 5 STATO Ontology Mapping and found no listings for Risk of Bias codes. We started mapping some Study Design terms. Meeting ended early to allow participation in Workshop on COVID-19 Ontologies.

October 30, 2020

We updated the Step 5 NCIt Ontology Mapping for Risk of Bias codes. 17 of 170 Risk of bias codes were mapped to entries in NCIt. Meeting ended early to allow participation in Workshop on COVID-19 Ontologies. (WCO-2020)

Archived Attendance List Prior to 10/19/20

People signed up to contribute or joining the meetings (**bold** if signed up as organization) or to be informed of this work group's progress. Starting 10/19/2020 Attendance can be found here.

Name	Organization	Email	Attendance
Brian Alper	**Computable Publishing**	balper@computablepublishing.com	703, 710, 717, 724, 731, 807, 814, 821, 828, 904, 911, 918, 925, 1002, 1009,1016
Khalid Shahin	**Computable Publishing**	kshahin@computablepublishing.com	807, 814, 821, 911, 1009, 1016
Eitan Agai	**PICO Portal**	EitanAgai@gmail.com	
Louis Leff	**EBMcalc**	louis@EBMcalc.com	
Joanne Dehnbostel	**Computable Publishing**	jdehnbostel@computablepublishing.com	0703, 710, 717, 724, 731, 807, 814, 821, 828, 904, 911, 918, 925, 1009, 1016
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Marty Mayer	EBSCO	mmayer@ebsco.com	710, 717, 731, 814, 821
Bhagvan Kommadi			1009,1016