## Questions for Evidence Extraction

<u>Meta-analysis</u> answers a research question of the form: "What is the impact of [some <u>predictor</u> or intervention of interest] on [some <u>outcome</u> of interest]?" Your research question is,

"What is the impact of a vegetarian diet on the overall mortality rate due to all causes?"

This form guides the process of extracting evidence from written reports of research findings for meta-analysis. It has two parts. The first part documents study-level information which includes details about each written report.

## Study-Level Information

In this section, you will document information about the written report you are coding. **Please** feel free to use shorthand or copy and paste blocks of text from the article itself.

Study Identity

1.	What is the title of the report?
2.	List the authors of the study.
3.	What year was the study published?
G	eneral notes:

## **Study Context**

Please use the following items to document the study design and the context of data collection, paying special attention to information that might impact how you interpret the study results.

1.	What kind of study is this?					
		Experimental (i.e., participants randomly assigned to groups)				
		Observational (i.e., participants' behavior was observed without intervention) $\downarrow$				
		Did the study use a control group to establish a baseline measurement of the outcome without intervention?  — Yes  — No				
		The groups of interest for the study are defined based on:  Exposure to the condition of interest (i.e., cohort study)				
		Exposure to the outcome of interest (i.e., case-control study)				
		Other kind of study ↓				
		Name:				
		Description:				
2.	What w	vas the study setting?				
		Controlled (e.g., clinic, laboratory)				
	_	Naturalistic (e.g., home, school, work)				
	_	Crowdsourced (e.g., webpage)				
		Other setting ↓				
		Name:				
		Description:				
3.	What v	vas the independent variable in the study, and how was it defined? Briefly describe				
	the inte	ervention and control conditions in the study.				
_						
G	eneral r	notes:				

# Participants

PΙέ	Please use the following items to describe participants in the study and how they were <u>selected</u> .				
1.	Briefly describe the process used to recruit participants for the study.				
<u> </u>	List any inclusion or evaluation evitoria that were used to filter out participants in the atual of				
2.	List any inclusion or exclusion criteria that were used to filter out participants in the study.				
3.	Briefly describe the <b>final sample of participants</b> after the recruitment and exclusion				
	processes in terms of relevant characteristics (e.g., demographics, occupation, health status). These are the people whose data are reflected in the results of the study.				
	status). These are the people whose data are reflected in the results of the study.				

### **Result-Level Information**

In this section, you will document information about each estimate of the effect of interest in the written report you are coding. Please fill out the questions in this section for each reported result you would like to include in your meta-analysis.

Note: Be careful not to create duplicate entries if the same results are reported in separate written reports.

How many results from this written report would you like to extract for meta-analysis?

#### Measurement

Please use the following items to describe how the outcome of interest was defined and measured in the study (i.e., how the outcome of interest is operationalized).

1.	What units of measurement were reported to quantify the outcome of interest?
2.	How did the authors obtain the reported measure? Please document how the author(s) define what counts as an observation of the outcome of interest.
G	General notes:

3.	was tr	ne outco	ome measurement taken <b>between-subjects</b> such that there is only one
	observ	ation p	er participant, or was the outcome measurement repeated within-subjects
	over ti	me sucl	n that there are multiple observations for each individual participant?
		The m	easurement was taken once per participant <b>between-subjects</b> .
		The m	easurement was repeated within-subjects.
4.	What v	was the	time schedule for measurement in the study? When were measures taken?
		The m	easurement was taken at <b>one point in time</b> . ↓
		Do the	authors report the point in time when the measurement was taken (e.g.,
		duratio	on after the intervention of interest)?
			Not applicable.
			No.
			Yes. ↓
			Record the time:
			What unit of time is reported?
		The m	easurement was taken at <b>multiple points in time</b> . ↓
		Do the	authors aggregate measurements over time and present one overall
		measu	re, or do the authors report the measure at multiple durations after the
		interve	ention of interest?
			The measurement is aggregated over time.
			The measurement is reported for <b>multiple points in time</b> . $\downarrow$
			The authors may have reported on more points in time than you want to
			include in your meta-analysis. Use your discretion. Which points in time or
			durations after the intervention are you interested in documenting and
			potentially including in your meta-analysis?
			List the times:
			What unit of time is reported?
_			
G	eneral r	notes:	
i			

5.	Do the	authors report this measure separately for different groups of participants (e.g.,
	groupii	ng their sample by demographics or some other factor)?
		Group effects were <b>not reported</b> .
		Group effects were <b>reported</b> . ↓
		The authors may have reported on more group comparisons than you want to
		include in your meta-analysis. Use your discretion. Which group-level effects are you
		interested in documenting and potentially including in your meta-analysis?
		☐ I am only interested in the effect <b>aggregated across groups</b> .
		☐ I am interested in the effect in <b>different groups</b> . ↓
		List the grouping factors that are of interest (e.g., gender):
		For each factor listed above, what levels of the factor were reported?
_		
G	eneral r	notes:

## Effect Size

Please use the following items to capture, in as much detail as possible, information reported about estimates of <u>effect size</u>. You will almost certainly find this information in the Results section.

1.	What	statistic is used to report the effect size estimate? This might be the same as the unit
	of mea	asurement, or it might be derived from that measurement through a statistical model.
	a.	What kind of effect size statistic is this?
		☐ Mean difference
		□ Ratio
		☐ Correlation
2.	Was a	statistical model used to produce the effect size estimate?
		No
		Yes↓
	W	nat statistical model was used?
3.	How is	s the <u>reliability</u> of the effect size estimate reported? Please check all that apply.
		Confidence Interval ↓
		What is the confidence level?%
		Test Statistic (e.g., t-value or F-value) ↓
		What is the test statistic?
		How many degrees of freedom (df) are there?
		p-value
		Standard error
4.	What (	(if any) covariates were adjusted for in the statistical model that produced the result?
	These	are factors which the authors controlled for when calculating effect size.
	'on oral	noto a
G	eneral	notes:

5. Use this table to document the numerical effect size information reported in the written report. Note that the study authors may report more comparisons than the ones you will include in your meta-analysis. You will only be able to aggregate effect sizes from these comparisons if the same comparison is made in multiple studies. To save time, you should only fill in numbers which seem necessary to answer your research question.

Group	Time Point	Sample Size (n)	Effect Size Estimate	Confidence Interval (CI)	Test Statistic	Degrees of Freedom (df)	p-value	Additional info

General notes:							

# **Evidence Quality Assessment**

## Risk of Bias

Please use these questions to gage how well the study was conducted (i.e., internal validity). The subsections below reflect various threats to validity which could undermine the fidelity of effect size estimates.

C. V	lection	$\nu_{i}$
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	סום ווטו.					
1.	system	e recruitment process result in intervention and control groups that were natically different?  Yes				
		No				
		Not sure				
	This co	ould be an issue if, for example:				
	•	Intervention and control groups were recruited using a different procedures or inclusion criteria.  Participants in the study were volunteers.				
	•	The non-response rate to the recruitment message was different between the intervention and control groups.				
	•	The intervention and control groups were not recruited from the same population. The intervention and control groups were recruited at different times.				
2.	Did exclusion or attrition result in intervention and control groups that were					
	-	natically different?				
		Yes				
		No				
		Not sure				
	This co	ould be an issue if, for example:				
	•	Participants who withdrew from the study were systematically different from the final sample of participants.				
	•	Participants who were excluded from the study were systematically different from the final sample of participants.				
	•	The study authors handled missing data in a way that relied on strong and potentially unreasonable assumptions (e.g., an unreasonable <u>imputation</u> strategy).				
3.		e study fail to randomly assign participants to intervention and control conditions? Yes				
		No				
		Not sure				
	This co	ould be an issue if, for example:				

- The authors did not use a random or pseudo-random process for group assignment.
- The assignment process was predictable to participants or study personnel.
- The study was not an experiment.

4.	Did the study fall to control for contounding variables that could explain differences in the
	outcome of interest between the intervention and control groups?
	□ Yes
	□ No

This could be an issue if, for example:

■ Not sure

- The authors failed to measure known confounding variables.
- Potentially confounding variables were differently distributed within the intervention and control groups.
- The study authors did not control for known confounding variables by either matching the study groups on them or using them as covariates in a regression.
- The study authors attempted to control for a variable that was **not** a confounding factor in the intervention-outcome relationship (e.g., by <u>overmatching</u> or including a <u>collider</u> in their regression model).

#### Measurement Issues

1.	Did the	e study fail to isolate the impact of being in the intervention versus control group?
		Yes
		No
		Not sure

This could be an issue if, for example:

- Participants didn't stay in the group they were assigned to (e.g., by not adhering to a treatment schedule).
- The procedure for determining membership in the intervention and control groups involved a subjective judgment on the part of study personnel.
- The procedure for determining membership in the intervention and control groups involved unverified recall and/or self-report on the part of the participant.
- Study personnel were not blind to group membership and treated participants differently depending on whether they were in the intervention or control condition.
- Participants were not blind to group membership and changed their behavior to satisfy the expectations of study personnel.

<ol> <li>Did the student</li> <li>Yes</li> </ol>	dy fail to detect or measure the outcome of interest?	
☐ No	•	
	sure	
	be an issue if, for example:	
	•	
	erent procedures were used for measuring the outcome of interest in the	
	rvention and control groups, respectively.	
	e procedure for measuring the outcome of interest involved a subjective	
	gment on the part of study personnel.	
	e procedure for measuring the outcome of interest involved unverified recall  I/or self-report on the part of the participant.	
	·	
	e outcome of interest was already present at the start of the study (e.g.,	
-	ticipants in a study on weight loss were already at a healthy weight).	
	e follow-up period in which measurements were made was not long enough to	
	w the outcome of interest to occur (e.g., a study of cancer risk that only	
	asures the presence of cancer for two months after intervention).	
	ticipants were previously exposed to conditions that would impact the	
oute	come of interest.	
Reporting Bias		
Did the stu- narrative?	dy authors seem to selectively report findings to support a particular	
☐ Yes		
□ No		
□ Not	sure	
This could be an issue if, for example:		
<ul><li>Not</li></ul>	all outcomes described in the study's methods were reported in the results.	
• The	study was funded or run by an entity that has an incentive to report a	
pan	ticular result.	
• The	e authors did not adequately describe their procedures for data collection and	
ana	lysis such that an independent party to reproduce them.	
• The	e study authors seem to have stopped data collection early for benefit (e.g.,	

once they obtained a statistically significant result).

## Applicability

Please use these questions to gage how well the study applies to the situation about which you are trying to make an inference (i.e., external validity). The subjections below reflect various concerns which could limit the generalizability of the study findings.

1.	Was the study conducted under conditions that differ in important ways from the situation you are trying to make an inference about?  — Yes		
	□ No		
	□ Not sure		
2.	Did the sample of participants differ in important ways from the population you are trying		
	to make an inference about?		
	□ Yes		
	□ No		
	□ Not sure		
3.	Was the intervention evaluated in this study different in important ways from the		
	intervention you are interested in making an inference about?		
	□ Yes		
	□ No		
	□ Not sure		
4.	Did the study compare the intervention of interest to a control condition that is different in		
	important ways from what would happen if you didn't intervene in the situation you are		
	trying to make an inference about?		
	□ Yes		
	□ No		
_	□ Not sure		
5.	Was the outcome measured in this study different in important ways from the outcome		
	you are interested in making an inference about?  ☐ Yes		
	□ res □ No		
	☐ Not sure		
	This might be an issue if, for example:		
	The follow-up duration in which outcomes were measured was not similar to the		
	timeframe about which you are interested in making an inference.		
	The study measured an outcome which was not of practical importance but was		
	thought to be a proxy for the outcome of interest.		

# **Coding Manual**

This manual describes the evidence we are looking for in each question of the evidence extraction form. Reference these descriptions for clarification and consistency as needed.

#### Study Context

1. What kind of study is this?

<u>Description</u>: We differentiate kinds of studies depending on the degree of control the authors exert on the situation under study. In experiments, the authors may <u>assign</u> participants to treatment and control groups and attempt to isolate the effect they are measuring through <u>experimental control</u>. In observational studies, the authors measure the situation under study in the real-world without exerting their influence. In most observational studies, there should still be a control group whose experience reflects the absence of the intervention or treatment of interest without <u>random assignment</u>.

<u>Location</u>: Articles will often explicitly state what kind of study was run, usually in the Method section. <u>Importance</u>: When comparing studies, we will want to consider whether different kinds of studies yield different patterns of results.

2. What was the study setting?

<u>Description</u>: Studies present data gathered in different kinds of settings or environments. A controlled setting is one in which the authors have attempted to isolate the effect of interest by eliminating factors that might exist in real-world situations. In contrast, a naturalistic setting is one in which the authors have exerted no influence and are taking measurements in the real world. A crowdsourced setting is one in which data is collected online.

<u>Location</u>: Study settings will often align with the kind of study and should be reported in the Method section

<u>Importance</u>: When comparing studies, we will want to consider whether different settings yield different patterns of results.

3. What was the independent variable in the study, and how was it defined? Briefly describe the intervention and control conditions in the study.

<u>Description</u>: Studies typically measure the effect of some manipulation or intervention. The specific condition which is manipulated is called an <u>independent variable</u>. An independent variable is assumed to have an impact on the outcome of interest (i.e., <u>dependent variable</u>).

<u>Location</u>: Independent variables will often be mentioned throughout the paper but in particular in the Method and Results section.

<u>Importance</u>: When conducting a meta-analysis, we will want to make sure that each of the studies we include measure the impact of the same independent variable. Otherwise, it doesn't make sense to

compare them. We also want to make sure that the manipulation of the independent variable produces conditions similar to the situation we are trying to make an inference about.

#### **Participants**

- 1. Briefly describe the process used to recruit participants for the study. <u>Description</u>: We think of participants in studies as being <u>sampled</u> from a particular population. Populations are essentially groups defined by common characteristics. If the recruitment process in a study biases the sample to include or omit a particular kind of participant (i.e., <u>selection bias</u>), we want to document this information so we can reason about the population in the study. <u>Location</u>: Information about the recruitment process will often be reported in the Method section. <u>Importance</u>: The effect we are interested in might be different in different populations, so we will want to consider whether the studies we plan to combine are sampling such different populations that it doesn't make sense to aggregate their results in a meta-analysis.
- 2. List any inclusion or exclusion criteria that were used to filter out participants in the study. <u>Description</u>: We think of participants in studies as being <u>sampled</u> from a particular population. Populations are essentially groups defined by common characteristics. If a study excludes participants in a way that biases the sample to omit a particular kind of participant (i.e., <u>selection bias</u>), we want to document this information so we can reason about the population in the study. <u>Location</u>: Information about exclusions will often be reported in the Method or Results section. <u>Importance</u>: The effect we are interested in might be different in different populations, so we will want to consider whether the studies we plan to combine are sampling such different populations that it doesn't make sense to aggregate their results in a meta-analysis.
- 3. Briefly describe the **final sample of participants** after the recruitment and exclusion processes in terms of relevant characteristics (e.g., demographics, occupation, health status). These are the people whose data are reflected in the results of the study.

  <u>Description</u>: We want to document any characteristics reported about the final sample of participants that help us reason about the population they represent. This might be evidence that the sample is representative of the population we want to make an inference about or that the sample is not representative in some way.

<u>Location</u>: Information about study participants will often be reported in the Methods or Results section.

<u>Importance</u>: If the study participants are too different from the participants in other studies, it may not make sense to combine the results of these studies in a meta-analysis. If the study participants are too different from the population we are interested in making inferences about, the results from this study may not be applicable or relevant to our meta-analysis.

#### Measurement

- 1. What units of measurement were reported to quantify the outcome of interest? <u>Description</u>: Units of measurement refer to the way that the outcome of interest is reported in the study. This might be some raw measure such as the number of times an event occurred, or it might be some derived measure such as the rate at which an event occurred. <u>Location</u>: Measurement units should be reported in the Method or Results section. <u>Importance</u>: We want to consider units of measurement when appraising the practical importance of the effect size reported in the study. Studies will likely use different units, so we will probably need to standardize the effect estimates from different studies before we can directly compare them.
- 2. How did the authors obtain the values of the reported measure? Please document how the author(s) define what counts as an observation of the outcome of interest.

  <u>Description</u>: The first part of this question asks what was actually done to get the measurements reported in the paper? For example, the authors may have administered a survey, brought participants into the lab for data collection, or perhaps they retrieved data that had already been collected for another study. The second part of this question asks about the set of conditions that must be met in order for the authors to measure the outcome of interest. For example, the authors may choose to qualify what will count as an instance of the outcome of interest in order to scope their research. Otherwise, there may be limitations of the method of measurement.

  <u>Location</u>: This information should be reported in the Method or Results section.

  <u>Importance</u>: In order to compare results across studies, we want to know where the data came from and whether or not studies differ in their methods of measurement.
- participant, or was the measurement repeated within-subjects over time such that there are multiple observations for each individual participant?

  <u>Description</u>: Some studies involve <u>repeated measurements</u> from individual participants over time. For example, authors may administer a survey to the same person at multiple points in time. Common reasons that authors may take repeated measurements within-subjects are: to compare outcomes before and after an intervention; to compare outcomes at different durations after an intervention; or to <u>improve statistical power</u> of their study design to detect patterns. These within-subjects measurements are in contrast with between-subjects measurements which each individual is measured only once.

3. Was the measurement taken between-subjects such that there is only one observation per

<u>Location</u>: Whether a measurement is within- or between-subjects will be reported in the Method or Results section.

<u>Importance</u>: Whether measurements are taken within- or between-subjects is important to consider when deciding whether to aggregate studies in meta-analysis. It is best practice not to combine

studies that use repeated measures within individual participants with studies that make comparisons between individuals since these measurement strategies are thought to measure different things.

4. What was the time schedule for measurement in the study? When were measures taken?

<u>Description</u>: Some study authors may <u>stratify</u> their data based on time. For example, they may report a measure taken at different durations after an intervention or baseline event. When authors stratify their data by time, it is often because the timing of events is important to their research question or the domain of study.

<u>Location</u>: The timing of measurements will be reported in the Method or Results section.

<u>Importance</u>: To the extent that the time course of measurements vary across studies, this may be important to consider when deciding whether to aggregate studies in meta-analysis. If the timing of measurements is dissimilar across studies, combining them in a meta-analysis will yield a result that averages over different time courses of measurement. At best this adds noise to the analysis; at worst it obfuscates the meaning of the aggregated effect size (e.g., if the effect is thought to change over time).

5. Do the authors report this measure separately for different groups of participants (e.g., grouping their sample by demographics or some other factor)?

<u>Description</u>: Study authors may group or <u>stratify</u> their participants (e.g., by gender or age) and report effects within each group (e.g., presenting results in <u>contingency tables</u>). Authors create these groups by identifying factors or variables which are of interest in their analysis. Each of these factors has different levels or possible values it might take on. For example, for the categorical factor of gender, possible levels might be man, woman, or non-binary. For continuous factors like age, the study authors might create levels by <u>binning</u> their data into relevant age groups (e.g., 18-30, 30-50, 50-65, 65+) as a way of forming discrete levels. When authors present results for different groups, it is often because those grouping factors are thought to influence the effect of interest.

<u>Location</u>: Grouping factors should be reported in the Results section, but the rationale for their importance may be located elsewhere or may not be explicitly stated.

<u>Importance</u>: We need to decide whether these grouping factors are of interest for meta-analysis, or if we prefer to only document the overall effect. Even if we are interested in group-level effects, we will only be able to include them in our meta-analysis if they are reported across multiple studies.

#### Effect Size

Please use the following items to capture, in as much detail as possible, information reported about estimates of <u>effect size</u>. You will almost certainly find this information in the Results section. For each statistic reported about the effect of interest, please fill out the following items.

1. What statistic is used to report the effect size estimate? This might be the same as the unit of measurement, or it might be derived from that measurement through a statistical model.

<u>Description</u>: <u>Effect size</u> might be reported in any of the following ways:

- An average measurement in each group
- An average difference between groups
- A ratio describing the relative probability of the outcome of interest
- A <u>correlation coefficient</u> or <u>R-squared</u> value
- A regression coefficient

Location: Effect size should be reported in the Results section.

<u>Importance</u>: All of these different ways of reporting effect size represent the empirical results of a scientific study. They are estimates of the impact of the predictor or intervention of interest on the outcome of interest. These numbers are the primary information required for meta-analysis.

- 3. How is the <u>reliability</u> of the effect size estimate reported? Please check all that apply.

  <u>Description</u>: Reliability is an indicator of how repeatable the estimation process is. Reliability statistics answer the question: How likely is it that if we repeated the same analysis process, it would produce a similar effect size estimate? Reliability might be reported as a test statistic such as a <u>t-test</u> or an <u>ANOVA F-test</u>. Alternatively, it might be a <u>p-value</u>, a <u>standard error</u>, or a <u>confidence interval</u>.

  <u>Location</u>: Reliability should be reported in the Results section alongside the effect size estimate.

  <u>Importance</u>: We want to document reliability information so that we know how uncertain the results from the study are. We need to incorporate this error into our meta-analysis.
- 4. What (if any) covariates were adjusted for in the statistical model that produced the result?

  These are factors which the authors controlled for when calculating effect size.

  Description: Covariates are variables other than the predictor and outcome of interest which are included in a statistical model. Including these other variables in the model adjusts the effect size estimate for the influence of these covariates. Specifically, the model splits the data into groups for each level of the covariates, calculates the effect of interest in each group, and takes a weighted average of the effect size across these groups. Covariates might be demographic variables like age or characteristics like health status which impact both the predictor and the outcome of interest. Most regression models in particular will have covariates, but other kinds of models may not.

  Location: The authors should report covariates for each model in their Methods or Results.

  Importance: Studies adjusting for different sets of covariates will estimate different effect sizes. It is best practice not to combine effects which are adjusted for different sets of covariates.