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Information Management During A Complex Meta-Analysis Project: A Practical Guide for Organizing Data Extraction

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ABSTRACT

Information management is a key part of conducting a systematic review and meta-analysis. Preferred Reporting Items for Systematic Reviews and Meta-Analyses clearly summarizes essential steps during the meta-analytic project and their reporting. Preparing for data extraction is generally suggested to be done at the stage of the protocol. However, in complex projects that aim to synthesize data from studies performed over a long time period or with a wide variability in study protocols, it is often impossible to fully account for all variations in data presentation before completing the full text screening. Here, we describe a protocol to methodically consider different aspects of the selected studies in order to update the data extraction template for the meta-analytic portion of the project. The protocol incorporates a process of identifying and removing non-compatible studies prior to the extraction of study-level outcomes, which is important for avoiding a potential confirmation bias. Using this protocol in combination with a pre-established data coding scheme simplifies data extraction and informs the subsequent meta-analysis.

KEYWORDS
Meta-analysis, Protocol, Spacefight, Data Management

1 | INTRODUCTION

Conducting a systematic review and meta-analysis is a complex process that requires significant organizational efforts (1-3). Many steps of this process are described in detail and clearly summarized in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist (4), including steps for data extraction and coding (3) for which several specific protocols, such as TIDieR (5) and DECiMAL (6), have been developed. It is generally advised to specify data extraction items before the full text reviews (3). However, this requires a prior knowledge of all the relevant data types and dimensions which is not always possible, especially in projects with significant variability in individual study protocols, specific parameters that measure the

outcomes, or methodology used in different papers. In our experience, such projects involved studies analyzing data from a long time period with historical changes in experimental approaches (7-11), as well as projects aimed at summarizing the findings from basic science studies that use a variety of study designs aimed to understand the same or similar outcomes (12-14). Importantly, this variability often only becomes apparent after the full text inclusion is complete, making it difficult to prepare for this challenge. Having completed multiple meta-analytic projects on a diverse number of subjects (8, 10, 12-14), we report the protocol we developed to methodically screen the full text studies and update the coding table for extracting parameters for meta-analysis.

2 | THE PLACE OF THIS PROTOCOL IN THE META-ANALYSIS PROJECT

In meta-analytical projects, the authors expect that quantitative data are available for their research question. After screening the studies retrieved from the relevant databases, the researchers arrive to a set of full text papers that can be small (7), reasonable with <50 studies (13-15), or quite large with 50-200 studies (8-10, 12). Even when the number of papers is small, each paper may contain multiple independent datasets of interest, such as measurements in different age, sex, or disease populations (13, 15). Further, the research question may be answered with a variety of different outcomes (7, 9, 15), dramatically increasing the complexity of information management. While general guidelines suggest that the next step is data extraction into the pre-defined coding tables, in many complex projects it is time-intensive, frustrating, and premature to engage in extraction of outcome measures at this stage. Instead, we suggest employing the following strategy that allows to update/develop coding tables focusing on the information most important for the meta-analysis project, while identifying incompatible studies prior to extraction of outcomes. This approach is important to prevent potential confirmation bias; that is, removing data that do not fit the hypothesis.

2.1 | STEP 1: Record key study characteristics and types of outcomes reported

With selected full texts retrieved, the key identifying characteristics of each study should be recorded such as: the author, year it was conducted, country where it was conducted, sample size, study type, population characteristics, etc. If PICO framework (P: Patient, problem or population, I: Intervention, C: Comparison, control or comparator; O: Outcome) (16) is used, this step focuses on the P of PICO. Assessment of study quality should be initiated as planned, in general using one of the established quality assessment tools that addresses potential biases relevant to their research question (2, 17). In addition, potential shortcomings of reporting specific to the current project may become apparent and can be included in the updated quality assessment checklist. The table resulting from this stage of analysis provides a general overview of the available information. Table 1 generated from our study of bone health in spacefaring rodents (9) illustrates how details important for the research project, such as the space mission, the year it was conducted, mission duration, the number of samples, and the bones measured were summarized. Please note, that while the coding table designed prior to the start of the project would always include general information (author, year, space mission), other details (such as the fact that different bone were analyzed in different studies) may not be known prior to full text analysis and are included at this stage.

2.2 | STEP 2: Identify studies reporting duplicate/overlapping information

In a systematic review, the reviewers may encounter several articles that report the outcomes of the same studies/populations that may not be apparent without careful analysis of full text articles. This may happen when the same results are reported together with dif-

ferent aspects of the whole study (8),when the updates for the same population are published during continuous recruitment (8), or when the same dataset is used for normalizing in the studies focused on different outcomes (18). While some authors clearly identify when the same findings are reported in subsequent papers, more often publications are treated as self-contained, and the reviewer needs to ensure that the datasets included in the meta-analysis are independent. Analyzing the table produced in the previous step helps to identify potentially overlapping studies that were conducted in the same year or location, have the same sample size, report identical measurement outcomes, etc. In our example (Table 1), the results of three space missions, STS-131, Bion-M1 and CRS10, were reported in multiple manuscripts. Comparison of the reported measurements demonstrates that Maupin et al. 2019 (19) and Dadwal et al. 2019 (20) report the outcomes in the same set of bones, while other studies report the parameters for different bones from the animals that went on the same missions. When two articles report overlapping data, one of the articles should be excluded from the meta-analysis based on a pre-defined criteria (for example, the one that includes less information, exhibits lower reporting quality, or achieves a lower quality score).

2.3 | STEP 3: Select parameters for analysis

Now we can determine which parameters have been reported in enough studies for meta-analysis and which measurements are compatible. If the dataset contains many different parameters, we suggest generating a new table where each parameter has its own column (Table 2). The same parameters can be given different names in different studies (due to different conventions in different groups or historical changes in nomenclature). Similarly, the same name can be given to different parameters. The same or similar parameters can also be measured using different methods. Keeping track of parameter definitions, measurement units and techniques allows to distinguish between different effect sizes. The table generated at this step allows to determine the number of instances the study-level outcomes are reported for each parameter, and thus the feasibility of a meta-analysis for different parameters. From the example in the Table 2, there is enough studies for meta-

Author, Year	Space Mission	Year	N	Bones Analyzed
Lloyd et al. 2015(21)	STS-108	2001	12	Vertebrae, Humerus, Femur, Tibia
Ortega et al. 2013(22)	STS-118	2007	13	Femur, Tibia
Tavella et al. 2012(23)	MDS	2009	3	Femur
Blaber et al. 2013(24)	STS-131	2010	15	Pelvis
Blaber et al. 2014(25)	STS-131	2010	15	Femur
Berg-Johansen et al. 2016(26)	Bion-M1	2013	30	Caudial vertebrae
Gerbaix et al. 2017(27)	Bion-M1	2013	30	Lumbar vertebrae, Femur
Gerbaix et al. 2018(28)	Bion-M1	2013	30	Calcaneus, Navicular, Talus
Shiba et al. 2017(29)	CRS-9	2016	12	Femur
Dadwal et al. 2019(20)	CRS-10	2017	10	Sternum, Vertebra, Tibia, Humerus
Maupin et al. 2019(19)	CRS-10	2017	28	Sternum, Vertebrae, Tibia, Humerus, Femur,
Tominari et al. 2019(30)	CRS-12	2017	3	Humerus, Tibia

TABLE 1 Example of the table describing details of the studies selected after full text screening for the project examining the effect of spaceflight on mouse bone tissue (9).

Author, Year	Space Mission	Bone Volume Fraction (BV/TV)	Marrow Area (Ma.Ar)	Cortical Porosity (Ct.Po)
Lloyd et al. 2015(21)	STS-108	Humerus, Tibia (NS)		
Ortega et al. 2013(22)	STS-118	Femur, Tibia (NS)		
Tavella et al. 2012(23)	MDS			
Blaber et al. 2013(24)	STS-131	Pelvis (%)		
Blaber et al. 2014(25)	STS-131	Femur (%)	Femur (mm^2)	Femur (%)
Berg-Johansen et al. 2016(26)	Bion-M1	Vertebrae (C) (%)		
Gerbaix et al. 2017(27)	Bion-M1	Vertebrae (L3,T12), Femur (%)	Femur (mm^2)	
Gerbaix et al. 2018(28)	Bion-M1	Calcanius, Talus Navicular, (%)		Calcaneus, Talus Navicular, (%)
Shiba et al. 2017(29)	CRS-9	Femur (%)		
Maupin et al. 2019(19)	CRS-10	Sternum, Tibia, Vertebrae (L4), Humerus (%)	Rib, Humerus, Femur, Tibia (mm^2)	
Tominari et al. 2019(30)	CRS-12	Humerus, Tibia (%)		
Number of Missions		**7**	**3**	**2**

TABLE 2 Example of the table describing several parameters reported in the studies selected to assess the effect of spaceflight on mouse bone tissue (9).

analysis of bone volume fraction in humerus, tibia, and femur and of marrow area in femur. However, there are only two datasets reporting cortical porosity in different bones. Thus, cortical porosity can be removed from the list of parameters to extract for analysis.

After candidate parameters for meta-analysis with at least three study-level outcomes are selected, we can determine whether measurements reported in different studies are compatible by comparing their measurement units and techniques. Ideally, the outcomes in all studies were obtained using the same methodology and reported on the same scale. However, in practice this may not be so, since meta-analyses often include papers performed at different times and places. Researcher must exhibit autonomous judgement for excluding certain studies as not compatible or choosing to combine the data while keeping track of implied assumptions and looking for opportunities to test them. For example, the relative amount of bone tissue (Bone volume/tissue volume, BV/TV %) can be obtained from 2-dimentional histological measurements or from 3-dimentional computed tomography. The studies reporting these outcomes could be designated as non-compatible, or the researchers can decide to combine them and explore in subgroup analysis if this introduces significant heterogeneity (7). At the end of this step, the set of parameters that will be included in meta-analysis is determined. All articles originally selected that do not report the chosen parameters or report incompatible outcomes (such as Tavella et al. 2012 in Table 2) will be excluded.

2.4 | STEP 4: Define important covariates

With a good idea about the content of selected studies, now the reviewer should update the coding table for the covariates that can potentially affect the outcome. While key parameters can generally be identified before the start of the project, now, when the differences between the included studies are recorded, ad-

ditional covariates may come into focus. Such covariates may be relevant to the specifics of included studies, such as genetic variants, surgery, treatment, measurement techniques, etc. Some covariates may make the data incompatible with the rest of the dataset, for example when something had happened in a small subset of studies and is biologically plausible to create significant difference in the outcome. The reviewer may decide to remove such articles as incompatible. The extraction table should be updated to include all the important covariates, which then can be analyzed during the meta-analytic study. The quality assessment checklist can also be updated for the quality of reporting of additional covariates.

2.5 | STEP 5: Extract relevant information, assess compatibility, and remove inconsistent reporting

Finally, the researcher has a template for extracting information regarding participants (step 1-2), outcomes (step 3) and covariates (step 4). It is a good practice to test this form by two independent reviewers, who later discuss disagreements and then adjust the form if necessary. Using the finalized template, the information can be extracted from all the papers, now together with the quantitative data for the study level outcomes and associated variance. Next, when the quantitative study-level outcomes are available and necessary data transformation is performed to ensure that units of measurements are consistent, we recommend checking for drastically different values. While it is wrong to exclude the study based on the difference in reported values, this may also be an indication of data extraction error. If no typing error was found, one should also check for potential discrepancy between the description and values given in the original paper, as mistakes in reporting do happen (we have encountered a study reporting a parameter as “normal”, yet the value was at least 1000-fold higher than normal). Attempts should be made to contact the author(s) and clarify these discrepancies. If efforts to contact the original authors are unsuccessful, it is safer to exclude the measured outcome or study than to make additional assumptions regarding the values. Final additions to the quality assessment checklist can now be made for the quality of the outcome reporting. Completing this step will result in having a dataset ready for quantitative synthesis using the meta-analytic model of your choice.

3 | CONCLUSION

We describe a protocol for information management during meta-analysis projects addressing research questions that involve variability in individual study approaches or methodologies that measure the outcomes. Such questions are more likely to arise in meta-analysis of basic science studies (2), which often employ exploratory methods rather than standardized clinical outcomes, and thus require a more open approach for managing the information to be included in the meta-analysis. Because of an open information management, the reviewers should at every step be cognizant of potential bias in their assessment, and carefully record the reasons for the exclusion of an individual study from the meta-analysis. Our protocol provides methodical guidelines for such an assessment, highlights potential difficulties that the reviewers may encounter, and suggests ways to address these difficulties in a clear unbiased way.

DECLARATION OF CONFLICTING INTERESTS

The Authors declare that there is no conflict of interest.

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