**Systematic Review Protocol**

**Recommended resources:**

* [Systematic reviews: Structure, form and content - PMC (nih.gov)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8406371/)
* [A step by step guide for conducting a systematic review and meta-analysis with simulation data - PMC (nih.gov)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6670166/)
* [An overview of methodological approaches in systematic reviews - PMC (nih.gov)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9322259/)
* [Systematic review protocol - outline/template (york.ac.uk)](https://www.crd.york.ac.uk/PROSPEROFILES/3611_STRATEGY_20130031.pdf)
* [PROSPERO (york.ac.uk)](https://www.crd.york.ac.uk/PROSPERO/#serviceinfopage)

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| Overview *– basic study information* | |
| Title of the review | Harmonizing Healthcare: The Art and Statistics of Consensus Building |
| Project title *(If different from review title)* | N/A |
| First reviewer | Joshua J. Cook, M.S. DS, M.S. CRM, ACRPM-PM, CCRC |
| Team of reviewers | Andrew Jimenez, M1, B.S.,  Achraf Cohen, Ph.D. |
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| Supervisor/project principal investigator | Achraf Cohen, Ph.D. |
| Organization(s) | University of West Florida, Georgetown University |
| Communication method | Discord - TBD  Google Drive ([CSP - Consensus Studies - Google Drive](https://drive.google.com/drive/u/0/folders/1L5fLWfHr2renmVKGnPIJi-AvabSo0Gni))  GitHub ([jjc54/ConsensusMethods: Literature and simulation (using R) resources for the study design and statistical analysis of RAND/UCLA Method (RAM) consensus studies. (github.com)](https://github.com/jjc54/ConsensusMethods)) |
| Review method *(PRISMA, PRISMA-P, Cochrane)* | PRISMA ([PRISMA statement (prisma-statement.org)](https://www.prisma-statement.org/)) |
| Funding mechanism | N/A |

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| Delegation *– management plan* | |
| Protocol Development | Cook, Jimenez, Cohen |
| Literature Searching | Cook, Jimenez |
| Data Extraction | Cook, Jimenez |
| Synthesis/Analysis | Cook, Jimenez, Cohen |
| Writing Up | Cook, Jimenez, Cohen |

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## 1. Background to Review

### 1.1 Important characteristics

*What are the important population and/or disease characteristics (diagnostic criteria, epidemiology, etiology, prognosis)?*

In the complex realm of medicine, it's essential to acknowledge that even seasoned practitioners may require guidance, especially when faced with uncertain or risky medical scenarios where traditional research methodology is deemed not feasible or unethical. Consensus statements are crucial tools for synthesizing expert opinions in such situations, offering a collective direction where singular expertise might be insufficient. However, there are several types of consensus studies, each with their own design schema and statistical guidelines that require deep understanding to ensure the validity and reliability of study outcomes.

### 1.2 Relevance

*Does the review topic have important implications for health (individual and/or public), as well as health care, policy and research?*

### 1.3 Rationale

*Does the evidence (including existing systematic reviews) fail to answer the review question, and why?*

### 1.4 Justification & Aim

*Is the need for the review justified in the light of the potential health implications and current limitations of the evidence base?*

This study provides a succinct guide to the intricacies involved in crafting consensus statements, addressing the definition of consensus, the optimal number of expert participants, and the balance between agreement and discussion rounds. We highlight the role of iterative feedback and the challenge of expert retention, supported by a systematic review of the existing literature and R simulations that assess the parameters that influence consensus achievement. Our aim is to serve as practical advisories for project managers and protocol writers, emphasizing that the process of reaching a consensus is not only iterative and collaborative but also integral to advancing medical practice and knowledge.

### 1.5 Specification

*What are the PICO (population, intervention, comparison, outcome) components of the review question / objective?*

## 2. Specific Objectives

1. To evaluate the existing available literature regarding the design of RAND/UCLA Appropriateness Method (RAM) consensus studies, with a specific focus on the statistical measures implemented to determine a consensus and ensure power, replication, and validity.
2. To collect study design and outcome data from the included studies to build a baseline probability distribution for use in simulation studies that will be focused on evaluating the influence of various study design characteristics on reaching a consensus.

## 3. Inclusion/Exclusion Criteria

### 3.1 Inclusion Criteria

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| --- | --- |
| **Population, participants and conditions of interest** | Physician or medical experts |
| **Interventions or exposures** | Any medical, clinical, or public health studies |
| **Comparisons or control groups** | N/A |
| **Outcomes of interest** | Number of included experts, expert background, number of rounds, number of discussions, consensus threshold, dropping of questions between survey |
| **Setting** | N/A |
| **Study designs** | RAND UCLA Appropriateness Method (RAM) consensus studies ([The RAND/UCLA Appropriateness Method User's Manual | RAND](https://www.rand.org/pubs/monograph_reports/MR1269.html)) |

### 3.2 Exclusion Criteria

*Any specific populations excluded, date range, language, region, full text availability, etc.*

* April 2019 – April 2024
* United States
* Any language if translation is available
* Free full text or institutional access
* “Modified” versions of RAND/UCLA unless altered methodology is clearly explained

## 4. Search Methods

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| **Electronic databases *(Highly suggested to include multiple, with data ranges searched for each)*** | PubMed  Cochrane  Google Scholar |
| **Key search terms, and method of identification of search terms *(must be sensitive and specific, can narrow down)*** | [litsearchr - an R package to facilitate quasi-automatic search strategy development for systematic reviews (elizagrames.github.io)](https://elizagrames.github.io/litsearchr/#tutorials) |
| **Other methods used for identifying relevant research *(i.e., experts, grey literature via CADTH, etc.)*** | N/A |
| **Journals hand searched *(include journals, date of search, and rationale for selection)*** | N/A |
| **Use of snowballing methods *(i.e., capture of citing papers)*** | N/A |

## 5. Methods of Review

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| **Details of methods *(At least 3 reviewers suggested, dealing with agreements and disagreements)*** | Three main reviewers (Cook, Jimenez, Cohen) and a third (librarian) to resolve any disagreements. |
| **Quality assessment *(tools or checklists used with references or URLs – CASP, AACODS)*** | We anticipate that most references will come from peer-reviewed published articles. Thus, we will use the Critical Appraisal Skills Programme (CASP) tool to assess the quality of the systematic review articles ([CASP Checklists - Critical Appraisal Skills Programme (casp-uk.net)](https://casp-uk.net/casp-tools-checklists/)). |
| **Data extraction *(information to be collected from each study, methods)*** | Data regarding the design and outcomes of the RAM consensus studies will be collected, including number of included experts, expert background, number of rounds, number of discussions, consensus threshold, dropping of questions between survey, whether a consensus was reached and on how many scenarios. This will be entered into Microsoft Excel. Reviewer number 1 will review first, followed by reviewer number 2 and 3,  which will be done independently. |
| **Narrative synthesis *(what and how synthesis will be done)*** | Narrative synthesis will be done alongside any meta-analysis and will be  carried out using a framework which consists of four elements;  1. Developing a foundation of common design characteristics of RAM consensus studies.  2. Developing a preliminary synthesis of findings of included studies  3. Exploring relationships within and between studies  4. Assessing the robustness of the synthesis |
| **Meta-analysis *(methods – Cochrane)*** | [Welcome! | Doing Meta-Analysis in R (bookdown.org)](https://bookdown.org/MathiasHarrer/Doing_Meta_Analysis_in_R/) |
| **Grading evidence *(system used, such as GRADE)*** | N/A |
| **Bias mitigation plan *(tools or checklists used with references or URLs – RoBiS/RoB 2)*** | RoBiS will be used to mitigate bias ([ROBIS: A new tool to assess risk of bias in systematic reviews was developed - PubMed (nih.gov)](https://pubmed.ncbi.nlm.nih.gov/26092286/)). |

## 6. Processes and Resources

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| **Background/expertise** | Study design, clinical research, data analysis, manuscript writing |
| **Computing facilities** | MacBook Pro 2023 |
| **Research databases** | PubMed, Cochrane, Google Scholar |
| **Bibliographic software** | Zotero |
| **Statistical software** | R/RStudio with associated packages |

## 7. Presentation of Results

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| **Additional material *(summary tables, flowcharts, etc. to be included in the final manuscript or associated database/GitHub)*** | Systematic review protocol template; simulation code via GitHub |
| **Outputs from review *(target conferences, journals)*** | Final Presentation – SRCOS 2024 Poster (03-04JUN2024; [SRCOS | Annual Summer Conference](https://www.srcos.org/conference))  Publication – Journal of Statistical Theory and Practice (CSP Invitation; [Home | Journal of Statistical Theory and Practice (springer.com)](https://link.springer.com/journal/42519)) |

## 8. Timeline for Review (*estimated*)

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| **Protocol development & registration through PROSPERO (**[**PROSPERO (york.ac.uk)**](https://www.crd.york.ac.uk/prospero/)**)** | 24MAY2024 |
| **Literature searching and study selection** | 31MAY2024 |
| **Study quality appraisal** | 03JUN2024 |
| **Data extraction** | 07JUN2024 |
| **Synthesis** | 21JUN2024 |
| **Writing up** | 28JUN2024 |
| **Draft manuscript for internal/peer review** | 05JUL2024 |
| **Submission for publication** | 30JUL2024 |