

## Journal of Human Lactation

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### Submission guidelines



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## Preparing your manuscript for submission

Your article must be within the scope of the journal and be of sufficient quality. If not, it will not be reviewed. Please read the journal's [Aims and Scope](#) to see if your article is appropriate.

The manuscript must be your original work, you must have the rights to the work, and you must have obtained and be able to supply all necessary permissions for the

reproduction of any copyright works not owned by you, including figures, illustrations, tables, lengthy quotations, or other material previously published elsewhere.

### Article types

To enhance the visual communication of research in JHL and to provide a consistent experience for our readership, JHL welcomes authors to submit a Graphical Abstract prior to final acceptance. Graphical abstracts must be designed and submitted by the authors at the time of final manuscript submission. Graphical abstracts should visually summarize the core message of articles in a concise format, in order to increase engagement, improve comprehension, and support promotion of your research. To aid in this process, we encourage authors to [download our graphical abstract template, and to please read JHL's graphical abstract guidelines for authors](#)

[Please review the article types table](#) for an overview on the word count and other required elements.

### ***A note on publishing for a lactation research journal.***

As a journal dedicated to the science of breastfeeding and lactation, *JHL* has certain requirements unique to this topic area.

We need only a brief summary of the benefits of human milk, as appropriate, at the beginning of the Background; however, the measurement of breastfeeding will need to be quite accurate in the Methods section. Authors should be specific about the use of banked or donated human milk and the equipment parents might be using, such as breast pumps, nipple shields, or supplemental nursing systems. For surveys, the specific question asked, who asked the question, and when, in the postpartum period, it was asked are both essential details. Definitions of exclusive, predominant, mixed, no breastfeeding, and weaning are required and need to be referenced using standardized definitions such as the World Health Organization.

The language of lactation can be challenging to navigate. Lactation refers to the maternal process alone, while breastfeeding can refer to the action of the parent, the child, or both [[Yourkavitch & Chetwynd](#), 2019]. We prefer 'human milk' to 'breastmilk,' 'breast milk,' or 'mother's milk.' The exception is when comparing a lactating mother or parent's own milk to human milk from others. The standard in these studies is to call the milk produced and fed within the gestational breastfeeding dyad to be 'Mother's Own Milk' or MOM and the milk of others labelled with details specific to its source (banked milk, donated milk, non-gestational parent's milk, or wet nurse).

If authors are submitting research on human milk, the collection, transportation, and storage can be affected in multiple ways. The specifics of these elements of the

research will be important to describe. Consider including the method of milk expression and how it was standardized among participants, whether one or both breasts were expressed, the time of day for milk collection, and the time since the last feeding or pumping session, among other relevant details.

The field of lactation support providers includes many types of service providers with varying training and scopes of practice. Thus, we cannot accept the term 'lactation consultant' or other general terms because they lack clarity within the field. Instead, be specific about the exact qualification of the support provider. We consider the International Board Certified Lactation Consultant to be an internationally recognized qualification. In other instances, the training received by support providers needs to be specifically stated.

The following editorials expand on the specific topic of writing for a lactation research journal.

- [Resiliency in Breastfeeding and Lactation Research: A Conversation About Scholastic Transparency, Bias, and Systems of Support](#)
- [The Gap Between Breastfeeding Research and the Clinical Needs of Lactation Support Providers](#)
- [The Art of Writing a Lactation Research Paper: Introducing New Author Directions at the \*Journal of Human Lactation\*](#)

## **1.5 Article Components for all types of articles**

Manuscript Components (common to most formats; check further instructions below and in table, above.)

### **1.5.1 Keywords**

During manuscript submission, enter 5-10 keywords into ScholarOne. Do not include these in the main manuscript file. One keyword must be "lactation" or "breastfeeding," and one must describe the methodology used (e.g., case-control, randomized controlled trial). Select keywords from a preselected list of lactation-specific keywords and MeSH (Medical Subject Headings) terms. You can use [MeSH on Demand](#) to identify suitable MeSH keywords for your manuscript. Verify your selected keywords on the MeSH [website](#).

### **1.5.2 Title page**

Submit the title page separately for anonymous peer review. This page should include:

- Complete manuscript title in APA formatting.
- Authors' full names, academic degrees, and current affiliations (candidacy for a degree is not appropriate to list). Also list any previous affiliations that existed during the time the study was conducted, if different than current affiliation.
- Identify the corresponding author's name, address, telephone number, and email address.
- Funding statement: All sources of funding including in kind contributions must be stated.

- Disclosures and conflict of interest statement: Include any additional information that could be important to the reader and promote transparency. This includes relationships between authors (e.g., student and advisor relationships).
- If this study (such as a clinical trial) or study protocol has been registered, provide registration information here.
- Acknowledgements: Less than 50 words is optimal. If a name is listed, include what was done by that person. Acknowledge use of AI, [if appropriate](#).
- Word count for main manuscript (not including references, tables, figures or abstract)
- List all other publications or prior reporting of any of the data used in the manuscript.

### **1.5.3 Key Messages**

Provide 3-4 bullet points written as one to two short sentences for a general audience, without abbreviations, containing the following information:

- One statement about the context of the study describing the gap in the knowledge base that is the rationale for doing this study.
- 1-2 statements about the main findings of the study.
- One statement of the significance of the study (i.e., how does this research add to the existing knowledge base?)

These should be submitted in a separate file.

## **1.6 Article Components by Article Types**

### **1.6.1 Original Research**

#### ***All Observational Studies***

Abstract for all Observational Studies

The abstract has a strict 250 words limit. No abbreviations should be used in the abstract except for APA formatted statistical notations. Required bolded headings are:

- Background
- Research aim/question(s). Stated as aim(s) or question(s), not objectives, goals, or purposes.
- Method: Begin with the design statement. Sample information belongs here.
- Results: Findings from the study
- Conclusion(s): General statements only based on the findings, but do not include results here.

Background for all Observational Studies

- Succinctly summarize literature directly related to the study aims, including the gap addressed. Report any differences if these data have been used before.
- Describe the theoretical or conceptual framework used, whether from literature or original. Consider including a diagram as a figure.
- Describe the significance of the study to the field of human lactation.
- End this section with the study aims using the same words as in the abstract.

Methods (specific to study design; more information below)

Results (specific to study design; more information below)

## Discussion for all Observational Studies

- Avoid redundancy. Do not restate or repeat results in this section except to remind the reader when discussing a related point.
- Reference, when appropriate, literature cited in the Introduction.
- Provide alternative possible explanations for the current findings, including possible biases.
- Identify and integrate areas in which further study should be done throughout the section.
- Include possible reasons for study findings.
- Describe how the results of this study compare with the most relevant previous studies.
- Do not overstate generalizability of findings.
- Describe the strengths of the study.

## Limitations

- Describe study limitations due to design, measurement, implementation, data analysis, and context of the study.
- Describe how bias may have influenced the study
- Include a statement regarding any limitations of the generalizability of your findings

## Conclusions

- Summarize the main findings with several general statements.
- This section should only be one paragraph.

## ***Methods: Quantitative Observational Studies***

The Methods section is divided into the following subsections and all must be present:

- Research Design
  - Start this subsection with a statement of the research design using research terminology (e.g., prospective/retrospective, cross-sectional/longitudinal, observational, 2-group comparison, etc.) according to the [APA JARS \(Journal Article Reporting Standards\)](#) glossary.
  - Include a statement about the Institutional Review Board (IRB) approval of your study in this section with the date and name of the IRB, as well as the approval number. Anonymize the name of the Institutional Review Board during peer review.
- Setting and Relevant Context

The purpose of this subsection is to inform our readers about the socio-cultural and economic context of the study, along with how these affect breastfeeding. For example, how does the structure of the healthcare system benefit or disadvantage breastfeeding families? In this subsection authors should paint a picture of the geo-socio-cultural environment (e.g., socio-economic status of geographic area, cultural context of area), along with the breastfeeding landscape (average duration of breastfeeding, who breastfeeds and who does not, what resources are available to inform and provide care for breastfeeding mothers).

- Sample
  - Identify the target population, then the sample population (participants).

- State the participant inclusion and exclusion criteria.
- For a cohort study: Describe methods of follow-up.
- For a case-control study—give the sources and methods of case ascertainment and control selection with the rationale for the choice of cases and controls.
- For matched cohort studies, give matching criteria and number of exposed and unexposed.
- For a matched case-control study—provide matching criteria and the number of controls per case.
- Provide sample information here (*not in the results section*), including the method of sampling, sample size rationale (with a description of power analysis, if applicable ([Haile, 2023](#)), and the final sample size.
- Outline any compensation or payments made to participants.
- If a flow diagram is included (suggested for cross-sectional, case-control, and cohort studies) to clarify how the sample was obtained, cite the figure in this section.
- A statement confirming the adequacy of the sample size should end this section.
- **Measurement**
  - Clearly define outcome and exposure variables and how they were measured. Include descriptions of other variables (predictors, potential confounders, and effect modifiers, if any) in text, table format, or supplemental materials. Also give diagnostic criteria, if applicable.
  - Report category boundaries when continuous variables are categorized.
  - Provide quality indicators for all instruments. Include the type of reliability and validity evaluated and steps taken to insure both. If statistical tests were conducted for reliability, include the specific values (Resources: [Berndt, 2020](#); [Wambach, 2018](#)).
  - Describe efforts to address potential sources of bias.
  - If survey methods are used, provide enough information about these instruments to inform readers of the appropriateness of their use within your specific population. Consider adding a copy of the questionnaires/surveys used to the Supplementary Materials in ScholarOne and reference it in the text.
- **Data Collection**
  - Start this section with the dates of data collection, including only relevant dates (e.g., periods of recruitment, exposure, follow-up, and data collection).
  - Provide information about how informed consent was obtained, if applicable.
  - Describe in adequate detail who collected data and how.
  - Include how the participants' confidentiality was maintained and how data were kept secure.
- **Data Analysis**
  - This section should start with the methods used to describe the baseline characteristics of the study sample.

- Followed by individual descriptions of how data were analyzed for each research aim or question in the same order as stated in the background section.
- Include a rationale and any relevant information about your decisions to group individual variables into composite variables, indices or scales, and how these new constructs were evaluated.
- The analysis plan should include rationale for selection of statistical tests or why the tests are appropriate to address both the study aim/question and the level of measurement.
- When multivariable modelling is applied, the analysis plan should include a description of the modelling procedures, including how variables were entered and evaluated, the criteria used to control for confounding, and the criteria by which the final models shown in the results were determined.
- Describe any methods used to examine subgroups and interactions.
- Explain how missing data were addressed.
- Describe any sensitivity analyzes performed.

In most cases, 95% confidence intervals are preferred over the p-value for evaluating statistical significance. In the case of p-values, the analysis plan should state if values shown are one or two tailed.

#### Results

- For guidance on APA formatting for numbers and statistics see [APA Style Numbers and Statistics Guide](#)
- Structure this section according to each of the research aims. It is appropriate to summarize findings displayed in table(s) and/or highlight key findings.
- Summarize the characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders.
  - For a cohort study, report numbers of outcome events or summary measures over time.
  - For a case-control study, report numbers in each exposure category, or summary measures of exposure.
  - For a cross-sectional study, report numbers of outcome events or summary measures.
- Avoid repeating in text most findings displayed in tables.
- Every time you report a percent or a frequency (n) – you must report both; every time you report a mean (M) you need to also report the standard deviation (SD) as M(SD).
- Presentation of the results from logistic regression, Poisson regression, or Cox regression should be the exponentiated parameter estimate (i.e., the measure of effect: odds ratio, incidence rate ratio, or hazard ratio) and corresponding 95% confidence interval rather than the parameter estimate (Beta). Indicators of the goodness of fit of the model (e.g., a model log likelihood ratio for logistic regression) should be included. Give unadjusted estimates and, if applicable, confounder-adjusted estimates. Make clear which confounders were adjusted for and why they were included.
- Report other analyzes performed (e.g., analyzes of subgroups, interactions, and sensitivity analyzes).

#### *Additional information for clinical trials:*

- Pilot studies or secondary analyzes do not require registration; however, the parent study registration for all secondary analyzes should be specified with the registration number in ScholarOne and in a statement on the title page.
- All randomized controlled trials submitted for publication should include a completed [Consolidated Standards of Report Trials \(CONSORT\) diagram and checklist](#).
  - We require authors to register their clinical trials at an appropriate registration database databases identified by the *International Committee of Medical Journal Editors* current lists 15 acceptable registries (e.g., the [US ClinicalTrials.gov](#), the WHO's *International Clinical Trials Registry Platform Search Portal*). Pilot studies or secondary analyzes do not require registration; however, the parent study registration for all secondary analyzes should be specified with the registration number in ScholarOne and in the required statement on the title page.
  - It is preferred that data is less than 5 years old
  - Randomized controlled trials must report all important harms or unintended effects in each group (for specific guidance see: [Equator Network: CONSORT Harms 2022 Statement , explanation, and elaboration](#)).

#### **Additional paper components**

[TOC](#) [Key Words](#), [Title Page](#), [Key Messages](#), [Background](#), [Discussion](#), [Limitations](#), [References](#), [Figures](#), [Tables](#)

#### **Methods: Qualitative Observational Studies**

##### Method

The Method section is divided into the following subsections: All must be present in this order:

- Design
  - Start this sub-section with a statement of the research design using research terminology according to the [APA JARS \(Journal Article Reporting Standards\)](#) glossary. Identify the type of qualitative design being used ([Dodgson, 2017](#)).
  - Include a statement about the Institutional Review Board (IRB) approval of your study in this section including the date and name of the IRB as well as approval number. Anonymize the name of the Institutional Review Board during peer review.
- Setting and Relevant Context
  - In qualitative research, the context in which the study was conducted influences everything. Be sure to adequately address this section.
  - The purpose of this sub-section is to inform our readers about the socio-cultural and economic context of the study, along with how these influence breastfeeding. In this section authors should paint a picture of the geo-socio-cultural environment, along with the breastfeeding landscape (e.g., average duration of breastfeeding, who breastfeeds and who does not, what resources are available to inform and provide care for breastfeeding parents).

- **Sample**
  - Identify the target population then the sample (participants), and all inclusion and exclusion criteria.
  - Describe the participant recruitment process. Describe the study aims as conveyed to participants if different than written in the manuscript.
  - Provide sample information here (*not in the Results section*), including sampling method, sample size rationale, and the final sample size ([Gill, 2020](#)).
  - Outline any compensation or payments made to participants.
  - A statement about the adequacy of the sample size should end this section.
- **Data Collection**
  - Start this section with the dates of data collection; include only relevant dates, periods of recruitment, initial data collection, and follow-up, if applicable. *JHL prefers data less than 5 years old. Data older than this will be reviewed for relevance.*
  - Provide information about how informed consent was obtained.
  - Describe in detail who collected data and their qualifications.
  - The interview guide and demographic questions should be added to supplemental materials.
  - Describe in detail how data were collected. Include relevant contextual information like length of interviews, location, and extensiveness of engagement.
  - Describe how reflexivity was managed during data collection, including identifying the relevant characteristics of the research team members who might have influenced the interview process or the data analysis ([Dodgson, 2019](#)).
  - Include how the participants' confidentiality was maintained and how data were kept secure.
- **Data Analysis**
  - This section should start with how the baseline characteristics of the study sample were analyzed. *Demographic characteristics of study participants are required for publication.*
  - Next include individual descriptions of how data were analyzed for each research aim or question in the same order as stated in the Background section.
  - Provide enough detail about who analyzed the data and exactly what method was used. Cite a reference(s) for the method used.
  - Reference the required Data Analysis Structure table in this section. This table must include details of the coding/thematic analysis structure with definitions for each code/theme/category. Do not put quotes in this table; they belong in the text.
  - Trustworthiness should be addressed in this section ([Nowell et al., 2017](#)).

## Results

- Start this section with demographic information, with the header 'Characteristics of the Sample.'
- Use [APA formatting](#) for all quotes.

- Structure this section according to each of the research aims. It is appropriate to summarize findings displayed in table(s) and/or highlight key findings.
- Avoid repeating in text most findings displayed in tables.

**Additional paper components:**

[TOC](#) [Key Words](#), [Title Page](#), [Key Messages](#), [Background](#), [Discussion](#), [Limitations](#), [References](#), [Figures](#), [Tables](#)

**1.6.2 Methods: Reviews of literature, policies, or programs**

The Methods section is divided into the following subsections; all must be present and in this order:

- Design
  - Indicate if a review protocol exists, and, if available, provide registration information, including protocol registration number.
  - Start this subsection with a design statement describing the type (methodology) of review conducted.
  - Provide the rationale for choosing the type of review conducted in the second sentence.
- Sample: Defining the Articles Reviewed
  - Identify the sample selection inclusion and exclusion criteria, providing rationales for each. Describe the process of selecting studies; for meta-analysis indicate how many people or automated processes reviewed articles and if they worked independently.
  - The articles reviewed must be the most recent and relevant and must include articles published up to six months before submission.
  - State final sample size here.
  - A figure of a PRISMA diagram is required for systematic reviews and referenced in this section of the text.
- Data collection: The Search Strategy and Process
  - Start this section with the dates of the inclusion period of the articles reviewed and the date last searched.
  - Identify which databases were searched and the search terms were used. *JHL* requires a minimum of 4 databases to be searched, one of which must be the [Cochrane Database of Systematic Reviews](#)
  - For meta-analysis indicate if study authors were contacted to identify missing data or additional studies.
  - Add to supplementary materials a full electronic search strategy for all databases searched, including any limits used, so that the searches could be repeated.
- Measurement
  - Clearly identify and define all variables. Indicate if any assumptions and simplifications were made when defining variables.
  - Collect demographic information about the publishing journals, year of publication, research teams, country of origin, and institution of review articles.

- Describe the process used to extract the data from the chosen articles (e.g., piloted forms, independently, in duplicate).
- Describe processes (if any) for obtaining and confirming data from investigators.
- Describe how the variables have been categorized for analysis, including a rationale and any relevant information about your decisions to group individual variables and how these new constructs were evaluated.
- Describe the methods used to organize the data (e.g., matrices)
- Describe how data were summarized.
- Data Analysis
  - This section should start with the methods used to describe the baseline characteristics of the sample (e.g., demographic information about the publishing journals).
  - Two data summary tables are required. Both tables should follow the general directions for all tables including being uploaded as separate files during submission and reference in the text in this section. See examples for more information.
    - Table 1: Include each study's 1st author, date of publication, study aim/question, sample (brief description and N), and design (using research terms). Include citations for each of these studies.
    - Table 2: Include each study's 1st author and date of publication, variables measured, instruments used to measure each variable, and reliability and validity of each instrument ([Chetwynd, 2022](#)).
  - Internal methodological congruence for each study reviewed must be determined and reported. Internal methodological congruence refers to the unity and consistence between study aim, research design, measurement, and analysis.
  - Define how potential bias was evaluated. This includes all types of cultural, institutional, and systemic bias (e.g., methodological, economic, environmental, gender, racial).
  - For meta-analysis:
    - Describe the method used for assessing risk of bias of individual studies including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.
    - State the principal summary measures (e.g., risk ratio, difference in means)
    - Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I<sup>2</sup>) for each meta-analysis.
    - Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).
    - Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. ([Chertok & Haile, 2018](#))

## Results

- For meta-analysis:

- Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.
- For each study, present characteristics for which data were extracted (e.g., study size, (population, intervention, control, outcomes, and study type (PICOS), follow-up period) and provide the citations.
- Present data on risk of bias of each study and, if available, any outcome-level assessment.
- For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group; and (b) effect estimates and confidence intervals, ideally with a forest plot.
- Present results of each meta-analysis done, including confidence intervals and measures of consistency. A forest plot is useful to display this information.
- Present results of any assessment of risk of bias across studies.
- Give results of additional analyzes, if done (e.g., sensitivity or subgroup analyzes, meta-regression)

#### Discussion

- Summarize what is known and unknown about your topic as a result of your critical analysis of the literature.
- Identify study design and other methodological issues seen across the reviewed studies.
- Identify and integrate areas for which further study is needed throughout the section.
- Discuss the limitations of the body of literature reviewed, include the methodology, bias and topics within this body of literature, include areas/topics/approaches that were missing.

#### Limitations

- Describe the limitations of your literature review (not the studies reviewed) due to design, measurement, implementation, and context of the study, including how bias might have influenced your results.

#### **Additional paper components:**

[TOC](#) [Key Words](#), [Title Page](#), [Key Messages](#), [Background](#), [Discussion](#), [Limitations](#), [References](#), [Figures](#), [Tables](#)

#### **1.6.3 Methods: Insights into Practice and Policy**

An Insight into Practice and Policy manuscript focuses on an innovative clinical practice or a policy analysis of interest to lactation educators, clinicians, researchers, and public health professionals. It is NOT the purpose of this manuscript type to report research.

Ensure that submissions adhere to the structure presented below and contain all listed parts:

#### Abstract

The unstructured abstract has a strict 250 words or less limit. No abbreviations should be used in the abstract except for APA formatted statistical notations.

Key Messages: Are a separate file

- Provide 3-4 bullet points written as one to two short sentences each without abbreviations containing the following information:
- One statement about the context of this paper describing the gap in the knowledge base or issue the authors seek to address.
- One or two statements about the clinical innovations or policy analysis presented in the paper.
- One statement describing the significance of what this paper adds to the field.

#### Background

- Provide the gap in the current body of knowledge that is addressed in this paper.
- Provide the significance of this clinical innovation or policy.
- End this section with a concise purpose statement.

#### The Clinical Innovation or Policy

- Provide enough detail for readers to understand the innovation and your rationale for developing/creating the perspective.
- Include the advantages and limitations of your approach.
- Briefly describe what research could be done to test, describe, or better understand what you have presented.

#### Conclusion

- Provide a concluding summary no longer than one paragraph.

#### **Additional paper components:**

[TOC](#) [Key Words](#), [Title Page](#), [Key Messages](#), [Background](#), [Discussion](#), [Limitations](#), [References](#), [Figures](#), [Tables](#)

#### **1.6.4 Case Study**

Ensure that submissions adhere to the structure presented below and contain all listed parts:

##### Protection of Human Subjects

Institutional Review Board: IRB approval is not required for case studies. However, if IRB approval was sought then the name of the IRB, the date of review, and approval number must be in the manuscript where indicated by the directions below. Documentation of IRB approval or exemption may be requested by the editorial staff at any point.

- Patient Consent is required for case studies: Adequate documentation of participant consent must be obtained. Participants must consent to participation and approve of the manuscript as submitted. This consent must remain with the author(s); however, it can be requested by the *JHL* Editor in Chief at any time.

#### Abstract

The structured abstract has a strict 250 words or less limit. No abbreviations should be used in the abstract except for APA formatted statistical notations. Required bolded headings, which summarize the same section of the manuscript are:

- Introduction – What is unique about this case and why is it important within the socio- cultural context of the participant and family?
- Main issue – Important clinical findings and major lactation issue
- Management – The actions taken and outcomes
- Conclusion – What are one or more “take-away” messages?

#### Introduction

- Start with a brief summary as to why this case is unique in the lactation literature using current evidence.
- Socio-cultural context should be clearly described.
- End this section with a statement that clearly states that the person(s) discussed in this case has given written consent for publication of this case and has read and approved of the case as submitted. If IRB approval was sought then include date and name of the IRB as well as approval number. You should anonymize the name of the Institutional Review Board during peer review.

#### History and Observational Assessment

- Start this section with de-identified demographic and other relevant historical and observational information.
- Describe the main concerns and presenting signs and symptoms of the breastfeeding family.
- Relevant past intervention(s) and their outcomes should be outlined.
- End this section with a summary paragraph of the evaluation of the history and observational assessment.

#### Management

- Diagnostic testing and challenges should be in this section, if applicable.
- Describe types of interventions with specific time frames and rationales, including any referrals or consultations.
- Describe any changes made to the original management with their rationales.
- Describe all follow-up actions taken.
- Reference the timeline table/figure in this section. For more details about the timeline, see section below.

#### Outcome(s)

- Clinician and client assessment of outcomes belong in this section. It is appropriate to use quotes, as needed.
- Describe the extent to which the participant followed and tolerated the management plan.
- Describe any adverse outcomes and unanticipated events.

#### Discussion

- This section should be a critical analysis of the process and outcomes of the management.
- Explain how the case could be relevant to the current body of lactation literature.

- Discuss both the strengths and weaknesses of the management approach.
- Main 'take-away' lesson(s) learned.
- Provide rationale for any of your conclusions.
- Take care not to infer generalizability.

#### **Additional paper components:**

[TOC](#) [Key Words](#), [Title Page](#), [Key Messages](#), [Background](#), [Discussion](#), [Limitations](#), [References](#), [Figures](#), [Tables](#)

#### **1.6.5 Protocols**

##### Title Page

- The title should indicate that the paper is a protocol and include study design. (Example: The impact of X on Y: protocol for a randomized controlled trial)
- Provide registration information

##### Abstract

The structured abstract has a strict 250 words or less limit. No abbreviations should be used in the abstract except for APA formatted statistical notations. Required bolded headings are:

- Background – Context and rationale for study context of the participant and family?
- Research aim/question(s)– Stated as aim(s) or question(s), not objectives, goals or purposes
- Methods and Planned Analyses – Begin with design statement. Sample/setting information belongs here.
- Discussion – General statements only, no results should be presented here. Should include potential

##### Key Messages

- Provide 3-4 bullet points written as one to two short sentences each without abbreviations containing the following information: 1) gap in knowledge, 2) methodology used/proposed, and 3 potential significance of the study.
  - One statement about context of study describing the gap in the knowledge base that is the rationale for doing this study.
  - 1-2 statements about the core findings of the study.
  - One statement of the significance of the study (i.e., How does this research add to the existing knowledge base?).

Background, Methods and Results will be similar to the study type of the protocol with the following exceptions:

##### Methods

- Research Design
  - Describe the theoretical or conceptual framework used for this study. The framework can be from the literature or original. Strongly consider including a diagram of your framework as a figure.
- Setting and Relevant Context

- No changes from other research types
- **Sample**
  - No changes from other research types except that the tense will be future tense.
- **Data Collection and Monitoring**
  - Include a general description/overview of participant contact points, including intervention delivery, data collection, and follow-up. Description should include timing, who is conducting/delivering assessments and interventions, in what format/medium (e.g., in-person, via telephone, etc.), and any other relevant information. A figure should be considered to supplement a written description.
  - Include start date of study (month/year), current status (ongoing, what stage—data collection, analysis), and expected date of completion of data collection and analysis
  - Provide information about how informed consent was obtained, if applicable.
  - Data management: include how the participants' confidentiality will be maintained, how data will be kept secure, plans for data entry and data quality checks
  - Data monitoring: provide information about data monitoring procedures, including whether there is a data monitoring committee/board, composition of committee/board or who is participating in data monitoring and any relevant relationships to study sponsors/funding agencies, description of any planned interim analyses and stopping guidelines. If there are plans for auditing study conduct, please include information about this, including auditing body, relationship to investigators and study sponsor(s), and planned auditing activities/timeline. Authors may provide detailed information on study auditing and data safety monitoring in supplementary materials.
- **Interventions**
  - Include description of method of assignment/randomization to interventions for RCTs (including blinding to assignment, circumstances under which unblinding is permissible); for each intervention(s) in sufficient detail to allow for replication, including timing of administration and how and by whom interventions are delivered
  - Include any criteria for modifying or discontinuing intervention(s)
  - Include description of how adherence to interventions will be monitored and any steps that will be taken to improve adherence
  - Include any relevant concomitant conditions that may interfere with or influence intervention(s) and how/if these will be monitored/controlled (e.g., additional breastfeeding education participants may receive in setting in a RCT of a breastfeeding support intervention)
- **Outcomes/M Measurement**
  - Clearly define each variable measured including all outcomes, exposures, predictors, potential confounders, and effect modifiers (if any), and how and when these will be measured. Denote the principal time point or period of interest and principal outcome(s) of interest. Provide diagnostic criteria, if applicable. Include analysis metric (e.g., change from baseline, time to event) and method of aggregation (mean, proportion, etc.).

- Report category boundaries when continuous variables are categorized.
- Provide quality indicators for all instruments. Include the type of reliability and validity evaluated and steps taken to insure both.
- Describe any efforts to address potential sources of bias.
- If survey methods are used, provide enough information about these instruments to inform readers of the appropriateness of their use within your specific population.
- Consider using a table to summarize data in this section. If a table is used, please do not repeat information verbatim in text.
- Add a copy of the questionnaires/surveys used to the Supplementary Materials in ScholarOne and reference it in the text.
- **Planned Data Analysis**
  - This section should include a description of how data will be analyzed for each research aim or question in the same order as stated in the background section.
  - Include a rationale and any relevant information about your decisions to group individual variables into indices or scales and how these new constructs will be evaluated.
  - The analysis plan should include rationale for selection of statistical tests or why the tests are appropriate to address both the study aim/question and the level of measurement.
  - When multivariate modeling will be applied, the analysis plan should include a description of the modeling procedures, including how variables will be entered and evaluated, the criteria used to control for confounding, and the criteria by which the final models will be determined.
    - Describe any methods planned to examine subgroups and interactions.
    - Explain how missing data will be addressed (approach to imputation and sensitivity analyses).
- **Submission**
  - Contact EIC, Ellen M. Chetwynd, at [jhleditorinchief@ilca.org](mailto:jhleditorinchief@ilca.org) before submitting to gauge interest. Only protocols outlining very significant or novel research will be considered, and ideally when there are major implications for other researchers in the field (e.g., a RCT describing a protocol that would be useful for other researchers looking to replicate or expand upon work before the RCT is published in full form; sharing preliminary safety data that will be useful interim data for other researchers/clinicians).

### **Protocols for Systematic Reviews and Meta-Analyses (Methods Section)**

- **Research Design**
  - Start this subsection with a design statement describing the type (methodology) of review to be conducted. Provide the rationale for choosing the type of review conducted in the second sentence.
- **Sample Frame**
  - Identify the article/sample selection inclusion and exclusion criteria, providing rationales for each (e.g., study design, setting, time frame, years considered, language, publication

status). Describe generally all planned article sources (e.g., electronic databases, trial registers, grey literature sources).

- Search Strategy
  - Describe search strategy such that the search could be replicated
  - Identify which databases will be searched and the search terms to be used. *JHL* requires a minimum of 4 databases to be searched, one of which must be the Cochrane Database of Systematic Reviews (<https://www.cochranelibrary.com>)
  - Indicate if study authors will be contacted to identify missing data or additional studies
  - Add to supplementary materials a full electronic search strategy for all databases searched, including any limits to be used, so that they could be repeated.
- Data management
  - Describe how records and data will be managed throughout the review (software, etc.)
- Selection process
  - Describe the process that will be used for selecting studies (e.g., number of reviewers, whether they worked independently, quality criteria considered, e.g., GRADE) at each phase of the review (e.g., screening, eligibility, and inclusion).
- Data collection/extraction
  - Describe planned methods of extracting data from articles (e.g., forms, individuals involved, methods to ensure reliability-duplicate extraction) and any processes for obtaining and confirming data from investigators
- Measurement
  - Identify and define all variables that will be collected/abstracted (e.g., study design, year of publication, outcomes), any pre-planned data assumptions, and how variables will be categorized/simplified with rationale.
- Data Synthesis and Analysis
  - Describe the methods that will be used to organize the data (e.g., matrices) and how data will be summarized. For meta-analysis protocols, describe planned analyses, including principal summary measures (e.g., risk ratio, difference in means), methods of handling data and methods of combining data from studies, any planned exploration of consistency (such as I<sup>2</sup>, Kendall's  $\tau$ ), planned sensitivity or subgroup analyses, etc.
- Bias Assessment
  - Include plans for assessing publication bias across studies and within individual studies. Include how the strength of the body of evidence will be evaluated (such as GRADE).

## Discussion

- Avoid redundancy. Do not restate or repeat methods in this section.
- Include any issues expected to impact conduct of the study/analysis and how these will be dealt with.
- Describe strengths and limitations of proposed study design, planned measurements, analyses, and context.

- Describe how planned study is expected to impact field, relative to current evidence base. Identify areas for further study.

**Additional paper components:**

[TOC Key Words](#), [Title Page](#), [Key Messages](#), [Background](#), [Discussion](#), [Limitations](#), [References](#), [Figures](#), [Tables](#)

**1.6.6 "From the Field" Column Guidelines**

**Goal:** As the evidence base of the International Board-Certified Lactation Consultants (IBCLC) profession evolves, a distinct gap has emerged between the focus of research being conducted and the immediate evidence-based needs of clinicians who are providing direct support to breastfeeding families. The goal of this column is to bridge the current chasm between clinical utility and rigor of published research. This feature will address the research-to-clinical application connection.

**Topics:** To be discussed with the Editor in Chief and mutually agreed upon. Some examples include how to implement infant body work into clinical practice, flange fitting, building/integrating a multidisciplinary IBCLC practice, etc.

**Format:**

- APA format (e.g., paragraphs, heading structure, in-text citations, reference list, etc.)
- Double spaced 12 point font
- Word limit: This is somewhat flexible, as different topics may need more/less words to adequately address. Aim for <1500-2000 words.
- Headers should be based on the nature of your described application. However, generally, we expect a background section, a description of the application, and a conclusion/summary
- Back up factual statements with current (<5-10 years old) citations
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- Title page that should contain:
  - Title formatted: *From the Field: (your title here)*
  - Your name, affiliations and email contact information
  - Acknowledgements, Disclosures and Conflicts of Interest (if n/a: The author declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article), Funding (if no funding, "The author received no financial support for the research, authorship, and/or publication of this article.")

**Submission:** Submit your draft by uploading your submission to ScholarOne, <https://mc.manuscriptcentral.com/jhl>.

**1.6.7 "About Research" Column Guidelines**

**Goal:** The purpose of this column is to provide our diverse, international readership with up-to-date information about research methodologies or other aspects of research. It is designed as a teaching tool

to help non-researchers better understand these topics.

The column also serves to bridge the gap between research and practice, offering a translation of research methods for our readership of IBCLCs and other clinical practitioners who may be unfamiliar with the methodologies featured in the journal.

Contributions should be written with the understanding that readers may be new to research methods. The content should be accessible at a baccalaureate reading level and include sufficient detail to clearly explain the ideas presented.

**Topics:** To be discussed and mutually agreed upon with the Editor-in-Chief.

**Submission:** Directions for how to submit this manuscript to ScholarOne will be sent by our Managing Editor.

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#### **Main Document:**

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- **Font/spacing:** Use 12-point font, double-spaced.
- **Word count:** Aim for 2,000–3,500 words (flexible based on topic).
- **Resources:** Optional table of resources (APA format)

#### **Title Page:**

- **Title:** Format as About Research: [Your Title].
- **Author information:** Include name, affiliations, and corresponding author information
- **Transparency:** Conflict of Interest and Funding statements

#### **1.6.8 "Breastfeeding Measurement" Column Guidelines**

**Goal:** To provide our diverse, international readership with clear and up-to-date information about research methods specific to measuring breastfeeding and lactation.

The measurement of breastfeeding in clinical and research settings is an evolving area. This column is intended to support new researchers, as well as those new to the field, in contributing effectively to this area of study. It also serves as a resource for IBCLCs and other practitioners who may not be familiar with the research methods published in the journal, helping bridge the gap between research and practice.

Articles should be written in an accessible manner, and comprehensible to readers with a baccalaureate-level understanding. Explanations should be clear and detailed enough to ensure that readers can follow the ideas and concepts presented.

**Topics:** To be discussed and mutually agreed upon with the Editor-in-Chief.

**Submission:** Directions for how to submit this manuscript to ScholarOne will be sent by our Managing Editor.

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## Main Document:

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- **Font/spacing:** Use 12-point font, double-spaced.
- **Word count:** Aim for 2,000–3,500 words (flexible based on topic).
- **Resources:** Optional table of resources (APA format).

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- **Author information:** Include name, affiliations, and corresponding author information
- **Transparency:** Conflict of Interest and Funding statements

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