

Protocol: Scoping review of the association between complementary feeding, growth, and immune health in infants and toddlers—An EAACI guideline paper

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Abstract

The European Academy of Allergy and Clinical Immunology (EAACI) is currently developing guidelines on immunomodulation and nutrition. To inform these recommendations, a scoping review will be conducted to synthesize and map the available empirical evidence on how complementary feeding affects immune health in infants and toddlers to explore the association between complementary feeding during the first year of life and immune health outcomes in children up to 3 years of age. The scoping review will be conducted using the Preferred Reporting Items for Systematic Reviews and Meta-analysis Scoping Review Extension for scoping reviews (PRISMA-ScR) guidelines. We have developed inclusion criteria using the PCC (Population, Concept and Context) format: the population will include healthy infants; the concept refers to specific factors related to introduction of complementary feeding; and the context will focus on studies conducted in settings representative of everyday nutrition and feeding practices for infants and toddlers. Evidence sources include systematic reviews. We will search in MEDLINE and Epistemonikos. Data will be extracted using a standardized form developed in REDCap, and the findings will be synthesized narratively. Only published literature will be included in this systematic review. Therefore, no ethical approval is required. The final review paper will be published in a peer-reviewed journal. OSF registration DOI: [10.17605/OSF.IO/T5F8](https://doi.org/10.17605/OSF.IO/T5F8).

KEYWORDS

allergic rhinitis, allergy, asthma, atopic dermatitis, food allergy, Immunonutrition, systematic review

1 | INTRODUCTION

Immunonutrition can generally be defined as the study of the direct and indirect effects of dietary components, including macronutrients, vitamins, minerals, and trace elements on immune system development, functionality, and responsiveness. It is well accepted that long-term unhealthy dietary habits are associated with increased risk of chronic immune-mediated disorders and poor responses to infection.¹ While dietary effects on immune function are relevant at all ages, this is perhaps most important during the introduction of complementary foods where life-long immune regulatory networks and functional trajectories are established. However, international guidelines to inform clinical recommendations on dietary practices that provide optimal immune health benefits are lacking.

Many aspects of complementary feeding are crucial for immune health as the immune system of infants and toddlers is still developing.² Deficiencies in key nutrients can affect immune function, thereby increasing the risk of allergies, autoimmune diseases, and infections, including gastrointestinal and respiratory infections.³ In addition, a diverse, fiber-rich diet is thought to support a healthy gut microbiome, which plays a critical role in immune regulation and protection from allergic and autoimmune diseases.^{4,5} Appropriate nutrition in early childhood influences lifelong immune resilience, also reducing the risk of allergies and autoimmune diseases.⁶ Diet diversity and early introduction of food allergens during complementary feeding play a crucial role in preventing food allergy⁷ and support growth, while preventing both malnutrition and obesity.^{6,8}

The developmental origins of health and disease hypothesis⁹ suggests that early life nutrition may have an impact on the risk of developing disease throughout the life span.¹⁰ In particular, allergic diseases are an ever-growing public health concern worldwide with important impacts both on morbidity and mortality. Although food allergy guidelines recommend early food allergen introduction for food allergy prevention, the role of overall diet during the complementary feeding period on allergy and overall immune health outcomes is still unclear.

1.1 | Aim

To synthesize and map the available empirical evidence on the impact of complementary feeding on immune health in infants and toddlers (birth to 3 years). This review will inform EAACI immunonutrition guidelines on the topic.

2 | METHODS AND ANALYSIS

This article describes the protocol for a scoping review, with a mapping of the available evidence for immune health effects associated with distinct dietary components. A scoping review systematically identifies and maps the breadth of evidence available on a particular

Key message

This scoping review will provide important information for future guidelines on infant nutrition, growth, and immune health.

topic, explaining key concepts or issues and characteristics related to these concepts.^{11,12} We prepared a protocol adhering to guidance from the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) and Joanna Briggs Institute's guidance document^{13,14} allowing for a standardized, transparent, and reproducible reporting of systematic review protocols. The scoping review will be reported in accordance with the PRISMA Extension for Scoping Reviews (PRISMA-ScR) guidelines.^{11,15} The PRISMA-ScR checklist¹⁵ will be completed and included in the final document. Updates and deviations from the protocol will be described in the final paper. The protocol was registered in Open Science Framework (DOI: [10.17605/OSF.IO/T5F8Q](https://doi.org/10.17605/OSF.IO/T5F8Q)).¹⁶

The main research question is: *What is the available empirical evidence on weaning food/solid food/complementary foods/food combinations and immune health?*

2.1 | Study eligibility criteria

We developed inclusion criteria according to the PPC format for scoping reviews, where population (P) is combined with concept (C) and context (C).

2.2 | Participants

Participants undergoing complementary feeding between birth and 1 year of age (infants) and between 1 and 3 years of age (toddlers) will be included. Studies including older children will be considered only if separate data for healthy infants and toddlers are provided. Participants of any gender, ethnic background, with no underlying health conditions affecting feeding or immune health will be included, if complementary feeding were studied. Studies with any number of participants will be eligible. We will not include preterm and low-birth weight infants, children with or recovering from acute malnutrition and serious illness, children living in emergency conditions, or children who are disabled.

2.3 | Concept

The concept of interest in this review¹¹ is the introduction of complementary foods, solid foods, and non-milk fluids, encompassing various dietary components and complementary feeding models, including as follows:

Overall diet measures:

- Diet diversity
- Food quality (e.g., Mediterranean diet index/score, Dietary inflammatory index)
- Food/diet patterns (including vegan/vegetarian diets)
- Plant-based foods, overall and specifically unprocessed plant-based foods

Food intake

- Specific foods or food groups (e.g., nuts, seeds)
- Sugar

Timing and method of complementary feeding

- Timely introduction of food allergens
- Order of food introductions
- Complementary Feeding Models (Baby-led weaning (BLW), Baby-led introduction to solids (BLISS), Responsive complementary feeding (RCF), Non-responsive complementary feeding (NRCF), Traditional complementary feeding).

Food preparation and processing

- Home-cooked foods
- Ultra-processed foods
- Advanced glycation end products (AGEs)
- Macro and micronutrient intake
- Nutrient intake
- Fats/oils
- Fiber
- Protein sources
- Avoidance of unnecessary supplementation (e.g., nutrient supplements, fortified food products)
- Vitamin A, Zinc, Iron
- Individual micronutrient supplements
- Consumption of excessive supplements
- Selenium
- Food combinations for nutrient bioavailability (e.g., fat-soluble vitamins require fat).

Studies reporting on breast feeding, formula feeding, or food intake outside of the complementary feeding timeline will be excluded.

2.4 | Context

The review will focus on studies conducted in settings representative of everyday nutrition and feeding practices for infants and toddlers, ensuring the findings are generalizable to common community settings.

2.5 | Outcomes

Outcomes included different measures of immune-health outcomes:

Immune system

- Immune system development
- Type 2 inflammation

Gut microbiome

Disease outcomes

- Allergies development
- Eczema or atopic dermatitis, asthma and wheezing, food allergies, allergic rhinitis/rhinitis/seasonal allergies
- Auto-immune diseases
- Infection risk

Growth

- Growth patterns
- Obesity and overweight risk

2.6 | Study types and publication status

We will include published systematic reviews that evaluate the effects of weaning foods, solid foods, complementary foods, or food combinations on the immune system of infants and toddlers.

For each outcome, we will select the most relevant systematic reviews, based on their comprehensiveness and date of search. We will provide a description of the primary data, randomized and non-randomized evidence, included in each selected review.

Non-comparative studies, animal studies, case series or studies, expert opinions, and studies reported only as (conference) abstracts will be excluded. Only published papers will be included.

2.7 | Search strategy

2.7.1 | Systematic reviews

We will systematically identify the potentially relevant studies through a structured search strategy in relevant medical literature databases. We will use electronic algorithms introducing a combination of controlled vocabulary and search terms in the following databases: (i) MEDLINE (accessed through Ovid); (ii) Epistemonikos (See [Appendix S1](#) for the MEDLINE search strategy). We will adapt the search algorithms to the requirements of each database, and we will use validated filters to retrieve appropriate designs as needed. We will also review references of included studies and ask guideline panels for additional relevant studies that could potentially fulfill our eligibility criteria.

2.7.2 | Primary studies

RCTs and cohorts will be identified from the most comprehensive and up to date SRs (last 5 years).

We will also review references of included studies and ask guideline panelists for additional relevant studies that could potentially fulfill our eligibility criteria. The full search algorithms are provided in an online database ([Appendix S1](#); Search strategy). The search will be conducted up to November 14th, 2024 for systematic reviews. We will use EndNote software to create a database for the management of the search results and deduplication of citations.

2.8 | Study selection

We will systematically retrieve the relevant studies according to the eligibility criteria described above. Previously calibrated reviewers will screen the retrieved citations results based on the title and abstract. Two reviewers will independently confirm eligibility based on the full text of the relevant articles. In case of disagreement, the discrepancies will be resolved by consensus or by involving a third reviewer. The selection process will be summarized using a PRISMA flowchart.¹¹

2.9 | Data extraction and charting

We will use a self-developed extraction form in RedCap to collect data. Previously calibrated reviewers will extract the main characteristics of the included studies. To ensure accuracy, a different reviewer will independently verify the extracted data. Key characteristics of the included studies will be synthesized into descriptive tables and summarized narratively.

The following information will be extracted from each systematic review, when available: general information (author, year, reference, search date, and databases searched), study objective, study design, population (including age groups), concept, sub-concepts, specific interventions, outcomes, measures, risk of bias assessment (if conducted), risk of bias tools, GRADE assessment (if conducted), and setting (common everyday nutrition and feeding practices). From each individual study, from those systematic reviews prioritized, we will extract: concept, sub-concepts, country, year of publication, and sample size.

2.10 | Critical appraisal of individual sources of evidence

This scoping review is not designed to provide a definitive answer to a specific healthcare question. Given its objective to identify and describe the published literature on complementary feeding and immune health, we will not conduct a critical appraisal or risk of bias assessment of the included evidence sources. However, we

will extract information on whether a risk of bias assessment was performed, the tools used (if any), and whether a GRADE assessment was conducted by systematic review authors. This information may be of use to select and update certain reviews in the future.

2.11 | Data analysis, collating, summarizing, and reporting the results

A descriptive analysis of the included studies will be performed. We will describe the main characteristics of factors related to complementary feeding, including concepts, sub-concepts, specific interventions (as defined by study authors), years of publication, number of databases searched, specific databases, type of source evidence (e.g., RCTs, observational studies, case-control, cross-sectional), whether a risk of bias assessment was performed and the tools used (if any), whether a meta-analysis was conducted, whether publication bias was assessed, whether a GRADE assessment was performed by the systematic review authors, and the availability of detailed data. Additionally, we will include an evidence map to synthesize, identify, describe, and characterize the existing evidence on immuno-health outcomes in relation to complementary feeding factors. R software and Microsoft Excel will be used for data analysis and development of charts and visual summaries.

2.12 | Subgroup analysis

If possible, separate information will be summarized according to age group: infants (0–12 months) and toddlers (1–3 years).

2.13 | Data report

The evidence will be summarized in a comprehensive report, including: number of included studies, key findings and potential limitations, PRISMA-ScR flowchart,¹⁵ descriptive table of the included studies (including all data described in the previous section), evidence mapping with visual presentations of the review findings (e.g., bubble plots), references of the included studies, list of the studies excluded by full text assessment with reasons for exclusion.

2.14 | Patient and public involvement

No patients or participants were involved in the development of this protocol or the design of this study. However, patient and public representatives will be able to comment on the draft guideline recommendations prior to publication.

AUTHOR CONTRIBUTIONS

Carina Venter: Conceptualization; funding acquisition; writing – original draft; writing – review and editing. **Pablo Alonso-Coello:** Writing

– review and editing; formal analysis. **Jessica Beltran:** Writing – review and editing; formal analysis. **Javier Bracchiglione:** Writing – review and editing; formal analysis. **Karina Fernandez-Saenz:** Writing – review and editing; formal analysis. **Pau Riera:** Writing – review and editing; formal analysis. **Ivan Solà:** Writing – review and editing; formal analysis. **Stefania Arasi:** Conceptualization; methodology; writing – review and editing. **Roberto Berni Canani:** Conceptualization; methodology; writing – review and editing. **David Fleischer:** Conceptualization; methodology; writing – review and editing. **Ibon Eguiluz-Gracia:** Conceptualization; methodology; writing – review and editing. **Rosan Meyer:** Conceptualization; methodology; writing – review and editing. **Graham Roberts:** Conceptualization; methodology; writing – review and editing. **Franziska Roth-Walter:** Conceptualization; methodology; writing – review and editing. **Alexandra F. Santos:** Conceptualization; methodology; writing – review and editing. **Isabel Skypala:** Conceptualization; methodology; writing – review and editing. **Peter K. Smith:** Conceptualization; methodology; writing – review and editing. **Milena Sokolowska:** Conceptualization; methodology; writing – review and editing. **Maria J. Torres:** Conceptualization; methodology; writing – review and editing. **Emilia Vassilopoulou:** Conceptualization; methodology; writing – review and editing. **Jens Walter:** Conceptualization; methodology; writing – review and editing. **Liam O'Mahony:** Conceptualization; funding acquisition; writing – review and editing.

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PEER REVIEW

The peer review history for this article is available at <https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/pai.70145>.

DATA AVAILABILITY STATEMENT

Not applicable.

ETHICS STATEMENT

Ethical approval will not be required as this is a systematic review of already published data and no patient consent will be needed.^{17,18}

The results of this scoping review will be submitted for publication in an international peer-reviewed journal and scientific meetings.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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