COnsensus Guidelines for REsearch on Human MILK (COREMILK)

Executive summary

Human milk holds a unique position as both a human bodily fluid and a food source. Its composition provides crucial insights into maternal dietary and health status, and is linked to infant growth, health, and developmental outcomes. As such, human milk composition has increasingly gained research attention. However, interpretation, synthesis, and application of this work are currently hampered by inconsistent and poor-quality methodological reporting. Specifically, there is widespread under-reporting of the following crucial aspects of human milk composition research:

- Maternal, breastfeeding, and infant demographics.
- Sample collection methods (e.g. time of day, stage postpartum, hand vs. pump expression).
- Sample storage, thawing, and homogenisation methods.
- Use of skim vs. whole milk.
- Analytical methods (e.g. coefficient of variation, limits of detection).

The lack of consistent reporting across these domains undermines transparency, replicability, and the ability to include studies in evidence syntheses. Without dedicated reporting guidance, research in this area risks inefficiency, misinterpretation, and limited translational value.

We propose the development of a reporting guideline for human milk composition research, following the EQUATOR Network framework. Such a guideline will establish a minimum set of items required to ensure research can be correctly interpreted, replicated, included in systematic reviews, and translated into clinical practice. We believe that this is a necessary step to propel this kind of research forward, strengthening the evidence base needed to inform clinical and public health practice.

Methodology

Development of the COREMILK reporting guideline will follow established EQUATOR Network methodology for health research guideline development. The process will involve four key phases:

1. **Preliminary item generation**: An Executive Working Group of experts will be assembled to identify and draft an initial list of candidate reporting items based on literature review and professional experience.
   Expected time frame: July-December 2025

2. **Delphi consensus process**: Broader expert input will be gathered through two to three rounds of Delphi surveys. Participants will rate the importance of each item and provide feedback, with iterative refinement between rounds to move toward consensus.
   Expected time frame: January-March 2026

3. **Consensus meeting**: A virtual consensus meeting will be held with Executive Group and broader working group members (including key stakeholders) to finalize the guideline content, wording, and structure based on the Delphi outcomes.
   Expected Timeframe: April-May 2026

4. **Manuscript preparation and dissemination**: A reporting guideline checklist and accompanying Explanation & Elaboration document will be drafted, reviewed by the group, and submitted for publication in an open-access, peer-reviewed journal. The final guideline will be registered with EQUATOR and disseminated through relevant professional networks.
   Expected timeframe: June-December 2026

Throughout all phases, full transparency, open communication, and recognition of contributions will be prioritized.