

Ø ★ **③** Breastfeeding 1

Breastfeeding: crucially important, but increasingly challenged in a market-driven world



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This is the first in a Series of three papers about breastfeeding. All papers in the Series are available at https:// www.thelancet.com/series/ breastfeeding-2023

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(A J D Barros PhD MD, P A Ribeiro Neves PhD Prof C G Victora PhD MD); UNICEF. Malabo. **Equatorial Guinea** (F Bégin PhD): Windsor, CT, USA (D J Chapman PhD); Department of Maternal, Newborn, Child and Adolescent Health (Prof N Rollins MD), and Department of Nutrition and Food Safety (L M Grummer-Strawn PhD), WHO, Geneva, Switzerland; International Institute for Global Health, United Nations University, Kuala Lumpur, Malaysia (Prof D McCoy PhD); In this Series paper, we examine how mother and baby attributes at the individual level interact with breastfeeding determinants at other levels, how these interactions drive breastfeeding outcomes, and what policies and interventions are necessary to achieve optimal breastfeeding. About one in three neonates in low-income and middle-income countries receive prelacteal feeds, and only one in two neonates are put to the breast within the first hour of life. Prelacteal feeds are strongly associated with delayed initiation of breastfeeding. Self-reported insufficient milk continues to be one of the most common reasons for introducing commercial milk formula (CMF) and stopping breastfeeding. Parents and health professionals frequently misinterpret typical, unsettled baby behaviours as signs of milk insufficiency or inadequacy. In our market-driven world and in violation of the WHO International Code for Marketing of Breast-milk Substitutes, the CMF industry exploits concerns of parents about these behaviours with unfounded product claims and advertising messages. A synthesis of reviews between 2016 and 2021 and country-based case studies indicate that breastfeeding practices at a population level can be improved rapidly through multilevel and multicomponent interventions across the socioecological model and settings. Breastfeeding is not the sole responsibility of women and requires collective societal approaches that take gender inequities into consideration.

Introduction

Human infants (aged ≤12 months) and young children (aged 12-36 months) are most likely to survive, grow, and develop to their full potential when fed human milk from their mothers through breastfeeding¹ due to the dynamic and interactional nature of breastfeeding and the unique living properties of breastmilk.^{2,3} Breastfeeding promotes healthy brain development and is essential for preventing the triple burden of malnutrition, infectious diseases, and mortality, while also reducing the risk of obesity and chronic diseases in later life in low-income and highincome countries alike.^{1,4,5} Breastfeeding supports birth spacing because when the baby nurses from the breast the mother's body releases hormones that prevent ovulation, leading to lactational amenorrhoea.^{1,6} Breastfeeding also helps to protect the mother against chronic diseases, including breast and ovarian cancers, type 2 diabetes, and cardiovascular disease. 1,6 The substantial, positive, early-life effects of breastfeeding for children, mothers, families, and wider society are sustained over the life course7 with strong economic benefits. An estimated US\$341.3 billion is lost globally each year from the unrealised benefits of breastfeeding to health and human development due to inadequate investment in protecting, promoting, and supporting breastfeeding.8

When possible, exclusively breastfeeding is recommended by WHO for the first 6 months of life, and continued breastfeeding for at least the first 2 years of life, with complementary foods being introduced at 6 months post partum.9 Yet globally, many mothers who can and wish to breastfeed face barriers at all levels of the socioecological model proposed in The Lancet's 2016 breastfeeding Series.4

Key structural barriers that undermine the breastfeeding environment¹⁰ include gender inequities; harmful sociocultural infant-feeding norms;11 income growth and urbanisation;12,13 corporate marketing practices13 and political activities that weaken breastfeeding protection policies; labour markets that poorly accommodate women's reproductive rights and care work, reflecting major gender inequities; and poor health care that continues to undermine breastfeeding, including the medicalisation of birthing and infant care.14

These barriers exert a powerful influence on the main settings that influence breastfeeding: health systems, workplaces, communities, and households. Maternity care systems that do not follow the ten baby-friendly hospital initiative (BFHI) steps¹⁵ continue to undermine breastfeeding because BFHI practices have a crucial role in preparing for and supporting lactation. 15,16 Inadequate health-system support lowers the likelihood of breastfeeding due to poor staff training and marketing practices that are in violation of WHO's International Code for the Marketing of Breast-milk Substitutes¹⁷ (hereafter referred to as the Code), such as the distribution of commercial milk formula (CMF) samples and unjustified recommendations to introduce CMFs. 13,18-20 Absent, inadequate, or poorly enforced maternity protection policies also undermine breastfeeding among working women through poor access to paid maternity and paternity leave, flexible scheduling to accommodate breastfeeding, or appropriate breaks and facilities for breastfeeding or milk expression.^{21,22} For instance, literature from 2021 has emphasised that women working in the informal sector in the Philippines are not protected by maternity policies²³ although this might change as a result of the resolution published by the Commission on Human Rights in early 2022.²⁴ Communities and families often do not have the economic or educational resources and capabilities to adequately support breastfeeding.^{19,25,26}

At the individual level, attributes and interactions specific to mothers and infants, such as mental health challenges, anxiety about unsettled infant behaviours, self-reported insufficient milk (SRIM), and low self-efficacy are challenges to breastfeeding that have not been adequately addressed within health systems to date. 14,27,28

This Series provides a new vision on how to address breastfeeding protection, promotion, and support at scale through multilevel, equitable approaches. This vision addresses breastfeeding barriers and facilitators across all levels, from the structural to the individual, building on the conceptual model of the 2016 Lancet breastfeeding Series (figure 1). In this Series paper, we examine how individual-level parent and baby attributes interact with breastfeeding determinants at other levels of the socioecological model, how these interactions drive outcomes, and what policies and interventions are necessary to achieve optimal breastfeeding. Structural and settings-based barriers to breastfeeding, including commercial determinants, are expanded on in the second and third papers of this Series, 29,30 which analyse the marketing of commercial milk formula and the political economy of infant and young child feeding (figure 1).

The papers in this Series were developed with a combination of research methods: (1) analysis of national representative survey data of children younger than 2 years, (2) commissioned systematic reviews (appendix pp 1–7), and (3) commissioned case studies.

We use the terms women and breastfeeding throughout this Series for brevity and because most people who breastfeed identify as women; we recognise that not all people who breastfeed or chestfeed identify as women.

Scientific advances in breastfeeding, breastmilk, and lactation

Breastfeeding is part of our species-specific biopsychosocial system that has evolved through our mammalian history to optimise the health and survival of both mothers and infants.^{3,11} Research published since the 2016 *Lancet* breastfeeding Series¹ has strengthened the evidence for the importance of interactions between mother and baby during breastfeeding. For example, suckling the breast releases oxytocin, prolactin, and other metabolites that foster mother–child bonding and reduce physiological

Key messages

- Commercial milk formula (CMF) products and artificial formula feeding cannot emulate the living and dynamic nature of breastmilk and the human interaction between mother and baby during breastfeeding. The unique and unparalleled qualities of breastfeeding bestow short-term and long-term health and development benefits.
- Only half of newborn babies are put to the breast within the
 first hour of life, and about a third of babies in low-income
 and middle-income countries receive prelacteal feeds
 (mostly water and animal milk) before being put to the
 breast. Prelacteal feeding is strongly associated with
 delayed initiation of breastfeeding.
- Common infant adaptations to the post-birth environment, including crying, unsettled behaviour, and short night-time sleep durations, are often misconceived as signs of feeding problems. CMF marketing reinforces and exacerbates these misconceptions and makes unsubstantiated claims that CMFs can ameliorate these behaviours.
- Nearly half of mothers globally self-report insufficient milk (SRIM) as the primary reason for introducing CMFs in the first few months of life and for prematurely stopping breastfeeding. SRIM can generally be prevented or addressed successfully with appropriate support.
- Additional educational efforts are needed for health workers, families, and the public to inform them about normal early infant development, including common crying patterns, posseting, and short night-time sleep durations, to reduce the unnecessary introduction of CMFs and to prevent SRIM and early cessation of breastfeeding.
- Breastfeeding is not the sole responsibility of the mother.
 Reviews and country case studies indicate that improved breastfeeding practices at population level are achieved through a collective societal approach that includes multilevel and multicomponent interventions across the socioecological model and different settings.

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stress for both.31 Hormones in breastmilk stimulate appropriate infant appetite and sleep development, and hormonal, physiological, and metabolic changes during breastfeeding support the mother's lifelong health in various ways. During breastfeeding, the immune systems of mothers and infants communicate with each other beyond passive immunity,32 and mothers transmit elements of their microbiota to their children through breastmilk. These good bacteria live in the gut and help fight disease, digest food, and regulate the child's evolving immune system. They are influenced by several factors, including maternal diet and genetics, delivery method, antibiotic use, geographical location, and environment.^{2,3,33} If breastfeeding is undermined, these evolutionary benefits are lost, as are the unique adaptations of breastmilk and breastfeeding to the individual mother, infant, and their circumstances.

See Online for appendix

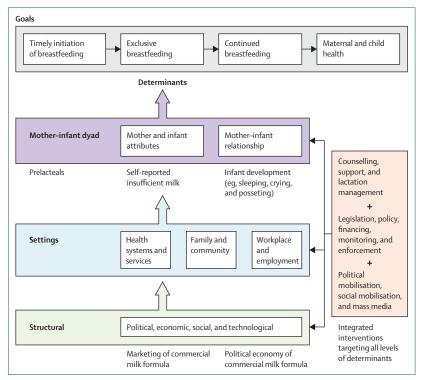


Figure 1: The 2023 Lancet breastfeeding Series framework

Breastfeeding is much more than the transfer of breastmilk from mother to baby. Suckling from the mother's breast is a crucial part of the nurturing of infants. Direct breastfeeding versus feeding breastmilk with a bottle, cup, or spoon has important implications for infant health and development. In addition to influencing infant craniofacial structure and reducing risk of malocclusion,34 there are newly recognised compositional differences in free amino acids and total protein in fore milk versus hind milk, and the probable retrograde flow of infants' oral microbiota into mother's milk that takes place during breastfeeding.35-37 The skinto-skin contact occurring through direct breastfeeding supports maturing mechanisms, including temperature control, metabolism, and diurnal adaptation. 16,38,39 Although the provision of expressed breastmilk in a bottle is superior to CMFs, direct breastfeeding compared with expressed breastmilk has been associated with lower rates of asthma, higher likelihood of the presence of the beneficial Bifidobacterium, and potentially better infant self-regulation of energy intake, thus protecting against obesity. 36,40,41

Breastmilk itself is a highly adaptive live food source^{11,42,43} and, because of its dynamic nature, is more than its nutrient components. Breastmilk comprises nutritive and non-nutritive bioactives (eg, hormones, immune factors, oligosaccharides, and live microbes) that collectively and through complex interactions with each other—and with the biological, social, and psychological

states of both mother and infant during breastfeeding—have a crucial role in healthy infant growth and development.^{2,3} Consequently, the composition of breastmilk changes during each feeding episode and as the infant develops over time, and in response to the physical and emotional state of the mother–child dyad. That the interactions and outcomes of breastfeeding cannot be artificially replicated is clear from past and new evidence.

Understanding breastmilk and the complex biopsychosocial system of breastfeeding

Since the publication of the 2016 *Lancet* breastfeeding Series,¹ discoveries have further shown how the nutritional, microbial, and bioactive components of breastmilk engage with each other, and how the composition of breastmilk varies with mother–baby interactions during breastfeeding. CMF and formula feeding cannot replicate the complexity and benefits of human milk and breastfeeding.

The specific bacteria found in breastmilk vary between and within populations, with several maternal and delivery-related factors influencing the variations in the predominant species.44 Some evidence shows the infant's oral microbiota might also contribute to the breastmilk microbiome, passing through the nipple into the mother's breast while breastfeeding. 35,36 Furthermore, the breastmilk microbiome contributes to the relatively low abundance of antibiotic resistance genes, particularly among infants breastfed for at least 6 months.45 Additional studies show that breastmilk extracellular vesicles contain at least 633 proteins that were previously not known to exist. These novel proteins appear to be involved in regulating cell growth and inflammation, and in signalling pathways that promote oral epithelial integrity.46,47 These extracellular vesicles also contain microRNA, which regulates gene expression that controls growth, inflammation, and the activation of T-regulatory cells, which in turn can protect against autoimmunity and necrotising enterocolitis. 48,49

The breastmilk microbiome and its vast array of human milk oligosaccharides have gained recognition for their interdependence and their effect on infant health; however, new findings regarding the free amino acid content of breastmilk show the multifunctionality of this previously overlooked component of the biological system. Glutamate and glutamine are the most abundant free amino acids in breastmilk, and together account for more than 70% of the free amino acids in breastmilk at any point during lactation. Research findings from multiple geographical locations indicate that the concentrations of several free amino acids (glutamine, glutamate, glycine, serine, and alanine) increase over the first 3 months of lactation, and free glutamine concentrations probably vary by infant sex. 75.051

Free glutamate promotes the growth of intestinal epithelial cells, whereas both free glutamate and free

glutamine have immunomodulatory actions and might modify the gut microbiota. ^{37,51} Furthermore, free glutamate concentrations are directly related to the rate of infant weight gain. ⁵²⁻⁵⁵ Given the dynamic variation in proportions of these free amino acids even within one mother–baby dyad, the addition of multiple free amino acids to CMFs cannot replicate the free amino acid profile of breastmilk, nor its effect on infants.

Likewise, only breastfeeding provides newborn babies, infants, and young children with protective antibodies acquired by maternal vaccines and the mother's own exposure to antigens and allergens. For instance, during the SARS-CoV-2 pandemic, numerous studies reported the presence of neutralising antibodies in breastmilk following vaccination or maternal infection. ^{56–58} Breastfeeding offers infants and young children their earliest form of immune protection against infectious disease. ⁵⁹

Although pioneering progress has been made over the past decade in exploring the biopsychosocial system of breastfeeding, we are only beginning to understand the complex biology of this unique functional food, and the social and psychological implications of breastfeeding interaction.^{2,3} To better understand the components of breastmilk, we need to clarify the roles and interactive relationships between several other components, including hormones (leptin and ghrelin), white blood cells, antimicrobial peptides, cytokines, and chemokines. The complex, interactive, and personalised nature of the biological system of breastmilk, and the unique and beneficial features of the breastfeeding relationship, are beyond replication.

Prelacteal feeds and early breastfeeding in lowincome and middle-income countries

Global trends in exclusive breastfeeding among children younger than 6 months and up to 2 years of age in low-income and middle-income countries (LMICs) were published in 2021.⁶⁰ High-income countries were not included because there is almost no nationally representative data on prelacteal feeds and early breastfeeding outcomes in these settings. However, less attention has been given to timely breastfeeding initiation (within an hour of birth) and prelacteal feeds (ie, foods other than breastmilk offered during the first 3 days after delivery^{61,62}) given to infants before the onset of lactation in LMICs. These practices influence breastfeeding success and neonatal mortality rates through complex and diverse pathways.⁶³⁻⁶⁵

Prelacteal feeds encompass a range of substances given to newborn babies consisting of water, milk, and milk-based substances, including CMF products. In LMICs, rice or maize water, sugar water, herbal mixtures, honey, ghee, and morsels of adult staple foods are also sometimes given. ⁶⁶ Some of these substances are intended to provide nourishment to a newborn baby, especially if colostrum is discarded. ⁶⁷ Others, such as

honey and dates, are given as part of cultural practices and as laxatives to clear meconium.⁶⁸ Even when immediate and exclusive breastfeeding is achieved, prelacteal feeds affect the neonate's establishment of normal microbiota in the gastrointestinal tract.^{69,70} Several studies report that the administration of prelacteal feeds delays breastfeeding, adversely affects lactation, and is associated with SRIM and premature supplementation or cessation of breastfeeding;^{71,72} a relationship investigated in this Series paper.

We used data from demographic and health surveys and multiple indicator cluster surveys (obtained from the International Center for Equity in Health database) to describe the prevalence and trends in early breastfeeding initiation and prelacteal feeding between 2000 and 2019 (figure 2). A total of 103 LMICs had nationally representative data on timely initiation of breastfeeding since 2010 (appendix pp 8–11). Fewer than half ($47 \cdot 2\%$) of all children in these countries were breastfed within the first hour of life. The lowest prevalence was reported in the Middle East and north Africa, and in the south Asia regions.

For 83 countries, time trends could also be described (appendix pp 12–24). The pooled prevalence of timely initiation increased from 29·7% (95% CI 21·7–37·7) in 2000 to 50·7% (95% CI 43·5–57·8) in 2019, or 1·1 percentage points per year, on average (appendix pp 25–37). Over the same period, exclusive breastfeeding at ages 0–5 months increased by 0·7 percentage points per year (0·51–0·88; p<0·0001) to reach 48·6% (95% CI 41·9–55·2) in 2019. Improvements were seen in all regions of the world except for the Middle East and north Africa, although the prevalence of exclusive breastfeeding is still far from the World Health Assembly goal of reaching at least 70% by 2030.60

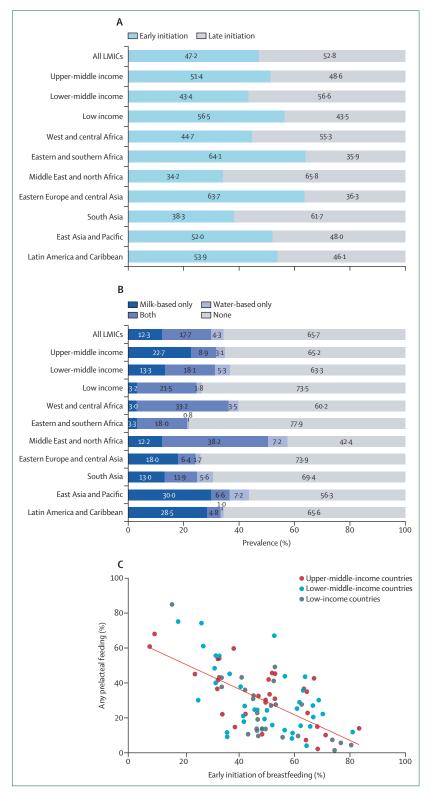
For all LMICs combined since 2010, $34\cdot3\%$ of children received prelacteal feeds including $12\cdot3\%$ who received a milk-based prelacteal feed only, $17\cdot7\%$ a water-based prelacteal feed, and $4\cdot3\%$ who received both. Milk-based prelacteal feeds were more common in higher-middle-income countries, whereas water-based prelacteal feeds were more common in low-income countries. We found a highly significant inverse correlation between early initiation of breastfeeding and use of prelacteal feeds in an ecological analysis of these data.

Unfortunately, national data on prelacteal feeding is not available for high-income countries, although numerous hospital studies report that CMF is given to breastfed newborn babies before discharge. The example, a study in the USA found that 62% of maternity facilities nationwide supplemented more than 20% of breastfed babies with formula during their hospital stay. Likewise, almost a third of newborn babies in Australia receive inhospital supplementation.

In summary, about one in three neonates in LMICs receive prelacteal feed substances during the first 3 days after birth, and only one in two neonates are breastfed within the first hour of life. The use of prelacteal

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feeds is strongly associated with delayed initiation of breastfeeding and can lead to the premature cessation of breastfeeding.



Infant behaviour, SRIM, and the early introduction of CMF

Humans are born in an immature state requiring intensive caregiving and remain immature for an extended period compared with other primate species.77 Metabolic and obstetric constraints, placental effects, and the adaptive importance of an extended period of social interaction and learning are the main explanations for these unique aspects of human development.77 Neonates rely on closeness to caregivers for survival and physiological regulation.77 Skin-to-skin contact and breastfeeding support maturing mechanisms, including temperature control, metabolism, and diurnal adaptation. 16,38,39 Because of their physiological immaturity, neonates are ill-equipped to deal with many sensory and other aspects of the postnatal environment (eg, feeding and sleeping) and express their discomfort in highly adaptive infant crying, which signals the need for help and support from caring adults.

Unsettled infant behaviours are the most frequent reasons for health consultations in the first months of life and are usually interpreted by mothers, their social networks, and frequently their health providers as signs of infant digestive problems, allergies, adverse reactions to breastmilk or a particular brand of CMF, or persistent hunger resulting from insufficient milk. Our systematic review of 22 studies across countries with different income levels concluded that unsettled infant behaviours, especially persistent crying, can lead parents to believe that CMF supplementation or specialised CMF formulas are needed.

Crying, fussiness, posseting, and short night-time sleep duration are common in early infancy. They are distressing for parents and are consistently reported to undermine parental self-efficacy. For example, up to 50% of healthy infants from birth to 3 months of age have at least one episode of regurgitation per day. A review of 28 diary studies found the mean time spent fussing or crying per day in the first 6 weeks of life was around 2 h a day, varying from 1 h to 3 h. Mean duration dropped rapidly after 6 weeks of age to about 1 h by 10–12 weeks of age. Interrupted night-time sleep, posseting, and crying often co-occur, 55,566 partly because crying frequently accompanies both infant waking and regurgitation. Even conservative estimates indicate that fewer than 5% of infants identified by parents as crying excessively are found to have any

Figure 2: Prelacteal feeding and early initiation of breastfeeding in LMICs Weighted by the number of children younger than 2 years in each country. (A) Early initiation of breastfeeding among children younger than 2 years by region. Early initiation of breastfeeding is defined as the proportion of children who were put to the breast within the first hour after birth. (B) Use of prelacteal feeds in 94 LMICs by income group and world region (appendix pp 38–41). Estimates were weighted by the population size of children in each country, obtained from the World Bank population estimates. (C) Correlation between prelacteal feeding and early initiation of breastfeeding, by country income groups. Pearson's r=-0-63 (p<0-0001). LMICs=low-income and middle-income countries.

underlying disease or illness requiring further investigation or treatment.^{80,87} Findings are similar for sleep patterns and posseting. Reports of objective measures of these infant developmental adaptations and parental anxiety are seldom found.^{88,89}

There are many reasons why infants cry, including hunger, changing temperatures, or other discomfort. Several parental responses successfully reduce crying: attending to immediate causes, such as a wet diaper; soothing and comforting techniques, such as carrying, rocking, and massaging; and feeding, especially breastfeeding, which involves close body contact, and suckling reduces distress and is incompatible with crying. However, in the absence of skilled and knowledgable support and reassurance, many parents change their feeding from breastfeeding to CMFs; from one CMF to another; or to specialised CMFs that, in violation of the Code, claim without evidence to reduce allergies, help with colic, and prolong night-time sleep (in the second paper in this Series).

Although understudied, behavioural cues of fussiness are commonly interpreted by parents, family members, and health-care staff as an indication that breastmilk quality or quantity is inadequate to satisfy their infant.^{75,96} CMF marketing messages exploit mothers' insecurities about their milk and their ability to satisfy and calm their baby^{97,99} by framing typical baby behaviours as pathological and offering CMFs as solutions (in the second paper in this Series²⁹). Hence, it is not surprising that SRIM is the reason given by more than half of mothers globally for introducing CMFs before 6 months post partum, and by a third of mothers for stopping breastfeeding.⁶²

SRIM has been conceptualised as "a state in which a mother has or perceives that she has an inadequate supply of breastmilk to either satisfy her infant's hunger and [or] to support her infant's adequate weight gain."100 Globally, 44.8% of mothers report introducing CMF because of SRIM.72 The extent to which SRIM is related to perceived or actual inadequate milk supply, milk nutritional quality, or both, has not been fully elucidated.^{72,80,101} Research indicates that a mother's self-assessment of milk supply is frequently based on perceptions of infant satiety and satisfaction, signalled by infant behaviours, especially crying and fussiness. 80,101,102 Inadequate lactation counselling and stress-management skills by health workers in the days after birth, together with misunderstanding among caregivers, family members, or health providers of the multifactorial causes of infant behaviours (eg, crying) and the marketing of CMFs as solutions to unsettled infants, can influence parents to introduce CMFs. Introducing CMFs can reduce suckling and can result in actual insufficient milk production. 65,103,104

Three systematic reviews found that the reasons for SRIM vary according to infant age, maternal characteristics, maternal mental health status,¹⁹ and stage of lactation¹⁰⁵ (ie, colostrum, onset of lactation, establishment, and maintenance of lactation). In a systematic review of

120 studies,72 key risk factors for SRIM were multilevel and multifactorial: (1) maternal socioeconomic psychosocial characteristics (eg, household income, maternal age, marital status, parity, education and employment status, self-efficacy or confidence in their ability to breastfeed, BMI, and weight gain during pregnancy); (2) delivery practices (eg, caesarean section delivery, prolonged stage II labour, use of pain medication or anaesthesia, and maternity hospitals that do not have good breastfeeding practices, such as putting the infant to the breast within the first hour post partum or skin-to-skin care), (3) breastfeeding challenges (eg, absence of previous breastfeeding experience, weak breastfeeding intention during pregnancy, having no access to breastfeeding support [especially in the days after birth], low frequency of nursing, maternal beliefs, and negative experiences with breastfeeding), and (4) baby behaviours (eg, fussiness and infant feeding difficulties, which can cause nipple pain and breast engorgement due to poor latching). 62,81

Since both prelacteal feeds and early introduction of CMFs are negatively associated with exclusive breastfeeding and breastfeeding duration, 61,62,71 mothers and health-care workers require better education on how to best address concerns about infants' developmental behaviours while maintaining successful breastfeeding. Infant developmental patterns and parental concerns about them need to be addressed through improved scientific study and public health practice to enhance breastfeeding guidance, starting in pregnancy and reinforced post partum. 65,106,107 Understanding how perceptions of infant behaviour influence caregivers' infant feeding decisions 22 and how such understanding can be used to improve breastfeeding support is important.

Globally, SRIM continues to be one of the most common reasons for introducing CMF and stopping breastfeeding.⁷² Parents and health professionals frequently misinterpret typical, unsettled baby behaviours as signs of milk insufficiency or inadequacy. In our market-driven world, and in violation of the Code,17 the CMF industry exploits parents with concerns about these behaviours with product claims and advertising messages. This marketing leads to early CMF introduction, which in turn reduces infant suckling and could also result in complete breastfeeding cessation. There widespread, unmet needs for exclusive and continued breastfeeding support in the face of these marketing dynamics and feeding challenges (in the second paper in this Series).29 With appropriate counselling support, in most cases effective breastfeeding and milk production can be increased and maintained.

Effective breastfeeding interventions to address health-care, social, and behavioural barriers

Building on evidence that breastfeeding rates can be rapidly improved by scaling up known interventions, policies, and programmes,⁴ we assessed the reviews published between 2016 and 2021 to provide more depth

and strengthen the evidence base for effective breastfeeding interventions, 108 many of which are needed to address the breastfeeding challenges described previously. We assessed the quality of reviews and their distribution across settings and elements of the socioecological model.

Consistent with *The Lancet's* 2016 Series' findings, research continues to focus on settings of high and upper-middle income (47 of 115 reviews, 41%), or a combination of settings with different income levels (48 of 115, 42%) that still tilts towards high-income countries even though the majority of births annually are in LMICs. Additionally, research remains primarily centred on health systems (72 of 115 reviews, 63%), followed by community and home settings (45 of 115, 39%), and the workplace (10 of 115, 9%). Few reviews (7 of 115, 8%) addressed structural interventions, a substantial gap discussed in the second and third papers in this Series.^{29,30}

In the workplace, evidence reinforces the importance of fully paid maternity leave in facilitating breastfeeding prevalence and duration, although disparities in access and utilisation persist109,110 and birth parents in the informal sector have little, if any, protection.26 Furthermore, to achieve equitable working conditions for breastfeeding mothers, organisational and social changes need to occur. 15 Workplaces could facilitate breastfeeding, especially when part of a broader set of parental support policies and practices. Written policies that describe the role of each actor (ie, managers and co-workers) in supporting breastfeeding in the workplace are particularly important.111,112 Given that many people in LMICs work in the informal economy or are not entitled to maternity benefits when they become unemployed, even if formerly employed in the formal sector (a situation that increased during the COVID-19 pandemic113), providing them with maternity benefits through cash transfers and other benefits is key. Research shows that this approach is feasible for middle-income countries such as Brazil, Ghana, Indonesia, Mexico, and the Philippines. 114,115

Within health systems, reviews have strengthened the evidence base for implementing early skin-to-skin care, ^{16,116} kangaroo mother care (ie, skin-to-skin with the mother or caregiver), ^{117,118} rooming in (ie, keeping the infant in the same room as the mother), ¹¹⁹ and cup feeding ^{120,121} at scale because these interventions consistently improved breastfeeding outcomes for both preterm and full-term infants. Implementation of the BFHI is also associated with better breastfeeding outcomes within the hospital and the community, which is not surprising given that it includes the interventions previously mentioned, allowing them to synergise with each other. ^{15,122-125}

These evaluations, together with country case studies, show the importance of multilevel and multicomponent approaches to create the enabling environment needed to effectively protect, promote, and support breastfeeding moving forward (discussed in the third paper in this Series³⁰). ^{28,126} Much of the innovation in interventions in the

past two decades has emerged via multicomponent programmes addressing the different domains of the socioecological model (figure 1). Robust evaluations show a greater effect on breastfeeding outcomes at scale than interventions that are not well coordinated across sectors and different levels of the socioecological model.^{127–130} For instance, BFHI can provide an important springboard for multilevel and multicomponent interventions that involve the engagement of community and individual families. 129-132 Community-based interventions could engage health-care providers, community health workers, and family members, 125,133 particularly fathers 134-136 and grandmothers, 137,138 with education and home visits that span the prenatal and postnatal periods. 124,139,140 Evidence indicates that home visits can be effectively provided by both trained health workers and community health workers. 141,142 Community health workers amplify networks of education and support across health-care, community, and family settings, 133 and might be particularly helpful in supporting historically marginalised communities143 and in complex situations like humanitarian emergencies. 127 Additionally, multicomponent interventions were particularly effective in achieving the greatest effect on breastfeeding outcomes, suggesting that discrete interventions complement each other. 128-130

The complexity and challenges involved in designing, delivering, and evaluating multicomponent breastfeeding support programmes that operate across the different levels of the socioecological model is important to acknowledge.4 Although much more implementation science research is needed, the evidence makes clear the importance for breastfeeding interventions to be multisectoral and rooted in sound health and social policies. For instance, efforts to improve early initiation of breastfeeding in Viet Nam have been designed in the context of high rates of births by caesarean section, an obstetric practice that is common in China and Latin America and becoming more common in sub-Saharan Africa.144 Despite achieving positive effects, efforts to improve exclusive breastfeeding in Viet Nam are also adversely affected by the mother's employment, especially when self-employed, which leads to feeding practices that combine breastfeeding with CMFs. This example further emphasises the importance of incorporating social policy change into efforts aiming to improve breastfeeding outcomes.145

Improvements to exclusive breastfeeding over the past decade

Several countries have translated knowledge into action to improve exclusive breastfeeding outcomes. 146 This section synthesises the findings and conclusions from case studies in Burkina Faso, the Philippines, the USA, and Mexico, commissioned for this paper by WHO. The methods and findings have been published elsewhere. 146 These countries were selected for geographical diversity (sub-Saharan Africa, Asia, North America, and Latin America), and for meeting the a priori selection criteria: 146 exclusive

breastfeeding rates increased in the past 10 years, breastfeeding policies and programmes were documented during the timeframe when breastfeeding outcomes improved (appendix pp 42–46), and a wide range of key informants were available for interview. Following the breastfeeding gear model¹²⁶ and the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) implementation framework¹⁴⁷ as a guide to analyses, we show the path that each country followed to improve exclusive breastfeeding practice.

Burkina Faso

Burkina Faso invested in training and programme delivery with a multilevel strategic plan (2012–25) to improve optimal infant and young child feeding practices, including at the community level, through the training of traditional leaders and the creation of mother-to-mother support groups. It has also promoted and mounted advocacy through government, UNICEF, and Alive & Thrive, including initiatives such as the Stronger with Breastmilk Only campaign to raise awareness of the importance of exclusive breastfeeding. This campaign promotes breastfeeding only, responding to the cues of the infant, and stopping the practice of giving water, other liquids, and foods in the first 6 months of life throughout west and central Africa.

The Philippines

Breastfeeding protection, promotion, and support is included in many national multicomponent policies and development strategies in the Philippines, reflecting political commitment. Additionally, there is commitment to including breastfeeding promotion, protection, and support as a part of national, cost-effective, time-bound, multicomponent packages such as early essential newborn care, an example of one of the specific investments that links the health provider with support for interpreting baby behaviour that affects early breastfeeding initiation. In addition, the Philippines has strengthened national legislation by approving and enacting the 105 day extended maternity leave law, which extends paid maternity leave from 60 days to 105 days, and the implementation of an official database of reported violations of the Code. 17 These efforts have been strongly influenced by breastfeeding coalitions that have actively resisted the CMF industry's political activities (in the third paper of this Series).30

The USA

Despite lacking a federally mandated paid leave, the USA has strong programme delivery coupled with regularly collected breastfeeding data reported annually by states. Local data serve as a basis for feedback to hospitals so they can implement evidence-based strategies to improve breastfeeding support. The USA continues to accredit an increasing number of baby-friendly hospitals each year. The Special Supplemental Nutrition Program for Women, Infants, and Children, which covers half of births in the

USA annually, is increasingly investing in breastfeeding counselling as it continues to change its benefits structure to support more mothers to choose breastfeeding rather than mixed feeding or CMFs. ¹⁴⁸ In addition, the 2010 Affordable Care Act expanded the number of people with health insurance and the US Department of Health and Human Services required health insurers to cover lactation support services, which has also improved coverage of breastfeeding support.

Mexico

Mexico implemented a national breastfeeding strategy (2014–18) to coordinate supportive actions. The becoming breastfeeding friendly policy toolbox^{149,150} has been applied three times since 2016 to strengthen policies and programmes to improve breastfeeding outcomes. Using this policy, the Mexican National Academy of Medicine issued its first position statement¹⁵¹ on the need to improve breastfeeding practices in Mexico. Scores were generated from the policy across eight domains: advocacy, political will, legislation, financial resources, workforce development and programme implementation, behaviour change communication campaigns, monitoring and coordination. evaluation. and Specific recommendations were made from the findings, including improved maternity benefits, workforce development, coverage and quality of BFHI, and decentralised coordination. Any breastfeeding, exclusive breastfeeding, and breastfeeding duration have improved since the launch of the first policy assessment. 152 Breastfeeding practices are monitored through nationally representative surveys, including the Health and Nutrition National Survey, the National Survey of Demographic Dynamics, and UNICEF's Multiple Indicator Cluster Surveys.

These examples show the importance of understanding breastfeeding behaviours and barriers in their local context and responding with multicomponent policies and programmes that involve both commitment and coordination among different sectors (government, international organisations, civil society, academia, and parents). The importance of robust data for monitoring, accountability, and programme adjustments is also emphasised. Political commitment in all four countries was key for improving exclusive breastfeeding, although in Mexico and Burkina Faso the budget allocation was clearly insufficient. In Mexico, the change of government affected the prioritisation of public health issues, including breastfeeding. Laws to protect breastfeeding were insufficient in all countries, but the Philippines had the strongest breastfeeding protection legislation related to the Code¹⁷ and maternity benefits. The advocacy of international and civil society organisations, and concrete actions to enforce the Code, were evident in Burkina Faso, the Philippines, and Mexico. Nevertheless, aggressive marketing by the CMF industry remains an enormous challenge for all four countries.

Discussion

In most cases, breastfeeding has a major positive effect on the health and wellbeing of infants and children, mothers, and society. Globally, most mothers can and are choosing to breastfeed, but many who can breastfeed cannot breastfeed for as long as recommended, even when they want to.153-155 Mothers and their families require support to be able to maintain breastfeeding while having the freedom and support to continue to participate in other areas of life as they choose, such as education and employment. 156,157 We know what needs to be done to improve breastfeeding outcomes: follow an approach that should be grounded in public health principles with an equity framework 10,158-163 and a human rights approach at its core. 164 To ensure all infants and young children receive the best possible nutrition and care there must be a society-wide enabling environment for breastfeeding, which is protected and sustained by political commitment, policies, and resources. 4,126

Discoveries in breastfeeding and breastmilk research highlight the large difference in quality between breastmilk and CMFs, leaving no doubt that breastfeeding promotes healthy and sustainable food systems.13 Since the 2000s, early breastfeeding initiation almost doubled globally, reaching 50% in 2019. Furthermore, over the past decade, exclusive breastfeeding among infants younger than 6 months increased by 0.7 percentage points per year, reaching 49% in 2019.60 Despite these important improvements, there are very few countries on track to meet the World Health Assembly target of 70% of infants being exclusively breastfed by 2030, and there are still large disparities across and within countries. 12,13,165,166 There are declining breastfeeding trends in low-income countries,60 mainly because infant and young child feeding practices are constrained and shaped by powerful structural influences, including social and commercial determinants, at all levels of the socioecological model (in the second and third papers of this Series^{29,30}). 11 Clearly, an approach by the whole of society is needed for mothers to be able to meet their breastfeeding goals.

It is of great concern that more than a third of all neonates received prelacteal feeds during the first 3 days after birth because this practice is negatively associated with timely breastfeeding initiation and breastfeeding duration. 61,71 An analysis by UNICEF and WHO 167 found that timely initiation rates are nearly twice as high among newborn babies who receive only breastmilk compared with newborn babies who receive milk-based supplemental feeds in the first 3 days of life. Health-system and community-based interventions are needed globally to prevent the introduction of prelacteal feeds and counteract the harmful influence of CMF marketing on health systems and communities.

At the dyadic and family levels, unsettled baby behaviours, including crying, posseting, and short nocturnal sleep duration, influence infant feeding decisions.³⁹ Although overwhelmingly an expression of

normal infant developmental processes rather than clinical conditions, these behaviours can prompt cessation of exclusive breastfeeding because they are interpreted by many parents as inadequate breastmilk supply or infant pathology requiring special feeding products. The CMF industry exploits and pathologises normal patterns of infant development in ways that exacerbate parental insecurities about feeding.^{97–99,168–170}

The misconception of typical human infant behaviour as pathological, and its exploitation by the CMF industry, are important factors of SRIM, which is a key reason for the introduction of CMF and the premature termination of breastfeeding. Preventing SRIM requires effective lactation management and social support during pregnancy, along with maternity facilities that follow policies and practices conducive to initiating breastfeeding without commercial influence. Supporting breastfeeding self-efficacy and combating CMF marketing influence through evidence-based information and support is paramount to preventing SRIM, the introduction of prelacteal feeds, or early introduction of CMF, which interfere with lactation.

For these reasons, universal access to improved breastfeeding-supportive maternity care, evidence-based breastfeeding counselling, and public and health worker education are crucial for preventing common early lactation problems, avoiding attempts to address common behaviours of infant developmental by introducing CMFs, and helping mothers improve their breastmilk production and self-efficacy. 62,65,101,171,172

The BFHI, community-based peer counselling, and maternity benefits for mothers working in both the formal and informal sectors are evidence-based approaches to improving breastfeeding outcomes. Protecting families from CMF marketing practices must take a comprehensive approach that addresses misleading advertisements and the CMF industry influence on health-care professionals and their societies, researchers, and the entire health-care environment (in the second paper of this Series).29 In agreement with previous reviews, 4,126 well coordinated, multicomponent, and multilevel programmes are the most promising approaches for scaling up and sustaining effective breastfeeding programmes, but more political commitment and financial investments are needed from governments. 4,146 Increased advocacy by international, civilsociety, and health-professional organisations must be translated into concrete legislative actions to implement. monitor, and enforce the Code, 17 and to remove the influence of CMF industry on SRIM and misinterpretation of infant development, mothers, health systems, and

Maternity protection policies have improved in the past decade due to national laws informed by the International Labour Organization standards, ¹⁷³ or via initiatives to improve breastfeeding environment at the workplace, but more progress is needed. Absent, inadequate, or poorly enforced maternity protection policies undermine breastfeeding among working mothers through

restricted access to paid maternity. For instance, in 2021, 649 million women of reproductive age lived in countries that do not meet the International Labour Organization standards for maternity leave (eg, a minimum period of 14 weeks paying the mother at least two-thirds of her previous earnings, covered by compulsory social insurance or public funds) and flexible scheduling to accommodate milk expression or breastfeeding.¹⁷³

In conclusion, much more is known now than previously about the biopsychosocial system of breastfeeding, and that it cannot be matched by CMF. A wealth of evidence shows how to create more enabling environments and deliver programmes to support breastfeeding at scale (panel). When direct breastfeeding is not possible, WHO guidance on infant and young child feeding should be followed to support responsive humanmilk feeding and any other replacement feeding as

Panel: Recommendations

The following policy and programmatic actions are needed to support mothers who want to breastfeed:

- Investment in public awareness and education is needed so
 that policy makers and the global general public recognise
 the growing scientific evidence that breastfeeding is the
 evolved, appropriate feeding system for optimising both
 mother and infant survival, health, and wellbeing.
 Misconceptions about the equivalence of commercial milk
 formula (CMF) to breastmilk must be corrected through
 extensive health education programmes directed towards
 the public and policy makers.
- Skilled counselling and support should be provided prenatally and post partum to all mothers to prevent and address self-reported insufficient milk and avert the introduction of prelacteal feeds or CMF early on, because they are major risk factors for the premature termination of exclusive breastfeeding and any breastfeeding.
- Health professionals, mothers, families, and communities
 must be provided with better educational support and skill
 development, free from commercial influence, to
 understand unsettled baby behaviours as an expected
 phase of human development. Health-care providers
 should offer anticipatory guidance, starting in pregnancy
 and continuing postnatally, to prepare mothers and other
 caregivers for how to respond to unsettled baby behaviours
 and industry marketing that misconstrues these behaviours
 and violates the WHO Code.¹⁷ This help will facilitate
 continued, successful breastfeeding.
- Intersectoral policies (eg, health, social development, education, labour, and regulatory sectors) that address multilevel barriers to breastfeeding must be implemented to enable mothers to breastfeed their children optimally for as long as they, or their babies, desire. These policies must be grounded in equity, human rights, and public health principles, and enabled through system-wide political and societal commitment for breastfeeding.

necessary. Long-term studies of national or subnational trends in breastfeeding are essential as we look ahead to the next decade. Special attention needs to be paid to the rapidly evolving and adapting marketing of CMFs, including through toddler and maternal milks, and through products targeted at the substantial proportion of small babies (eg, preterm and babies of low birthweight) born in LMICs (20% of babies born in sub-Saharan Africa and 30% in south Asia).174 These industry interventions deliberately violate the Code¹⁷ and prevent progress in improving breastfeeding outcomes globally.98,169 The second paper in this Series29 addresses how CMF marketing operates. The political and economic forces that enable this commercial influence and undermine breastfeeding in the context of major gender inequities are presented in the third paper of this Series.30

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RP-E developed the first draft of the manuscript. All authors contributed to the design, writing, and revision of the final draft of the manuscript. The authors alone are responsible for the views expressed in this article and they do not necessarily represent the views, decisions, or policies of the institutions with which they are affiliated.

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