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REVIEW ARTICLE

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Formula milk companies and allergy healthcare professionals in India

Hilary Allen[1] | Arun Gupta[2] | Alexandra Mundell[1] | Neeraj Gupta[3] | Anup Thakur[3] | Sowmya Nagarajan[4] | Daniel Munblit[1,5] | Phillip Baker[6] | Robert Boyle[1]

[1]National Heart and Lung Institute, Imperial College London, London, UK

[2]Breastfeeding Promotion Network of India, Delhi, India

[3]Department of Paediatrics, Institute of Child Health, Sir Ganga Ram Hospital, New Delhi, India

[4]Sanjeevini Specialist Clinic and KangarooCare Hospitals, Bengaluru, Karnataka, India

[5]Department of Paediatrics and Paediatric Infectious Diseases, Institute of Child's Health, Sechenov First Moscow State Medical University (Sechenov University), Moscow, Russia

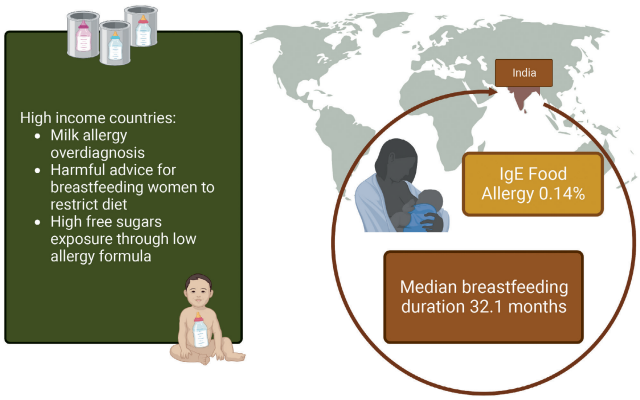
[6]Institute for Physical Activity and Nutrition, Deakin University, Geelong, Victoria, Australia

Correspondence
Robert Boyle, National Heart and Lung Institute, Imperial College London, Norfolk Place, Wright Fleming Building, London W2 1PG, UK.
Email: r.boyle@imperial.ac.uk

Abstract

India is a low-middle income country with a population of 1.4 billion and home to one quarter of the world's children. Exclusive breastfeeding until 6 months and continued breastfeeding until at least 2 years as per global recommendations are common practice. The Indian government and associated organisations have strived to protect breastfeeding, which is important in a country with high under-5 mortality, malnutrition and stunting. Allergic disease is under-recognised in India, but despite the absence of a dedicated allergy medical specialty, awareness of allergy is increasing among healthcare practitioners and in the general population. In high-income countries, overdiagnosis of allergy has become recognised as an issue in recent years. Allergy healthcare professionals have also attracted criticism for close relationships with the formula industry, which appear to have contributed to excessive use of specialised formula products and undermining of breastfeeding. Specialised formula has been used unnecessarily for preventing allergy, based on fraudulent and selectively reported science; and for managing normal infant symptoms which are mislabelled as milk allergy. This forms part of a broader formula industry corporate strategy to widen the boundaries of illness in order to expand sales and markets. In India, allergic disease management is hindered by limited understanding of the disease entity among practitioners, low access to diagnostics, limited healthcare resources, high exposure to air pollution and a large, diverse population. Data specific to India on allergic disease prevalence and interpreting allergy diagnostics are incomplete. The knowledge gaps mean allergy management in India is often extrapolated from guidance developed in high-income countries with low breastfeeding rates. As the allergy specialty develops in India, local guidance and practice will need to recognise the threat that current allergy practice poses to India's normative infant feeding culture, and ensure that breastfeeding continues to be supported at all levels.

KEYWORDS
breastfeeding, milk allergy, overdiagnosis, paediatrics



GRAPHICAL ABSTRACT

One quarter of children are born in India, where ~70% are breastfed for ≥2 years. Allergy practice in other countries has encouraged specialised formula overuse and contributed to undermining breastfeeding. Allergy practice and education carry potential nutrition and health risks for Indian mothers and infants.

1 | INTRODUCTION

A quarter of the world's children live in India, a country where breastfeeding has been well protected compared to some other regions of the world,[1] and formula milk sales remain relatively static. Allergic conditions, once quite uncommon in India, may be increasing in prevalence, and allergy awareness is certainly increasing, together with strengthened opportunities for undergraduate and postgraduate study of allergy by healthcare professionals.[2,3] In some high-income countries, the growth of paediatric allergy as a specialty in the early 21st century coincided with sharp increases in sales of low-allergy formula milk, to levels that exceed population requirements by 10-fold.[4] Conflictive relationships between formula milk companies and the allergy community have caused controversy due to breaching World Health Organization guidance on sponsorship of healthcare professional meetings.[5,6] There is growing evidence that excessive concern about infant allergy in high-income countries is serving to undermine mother–infant bonding, breastfeeding and child nutrition.[7]

In this article, we discuss the implications of this controversy for healthcare professionals in India. As the prevalence and awareness of allergic conditions grows in India, there is a danger that this will facilitate a shift towards suboptimal infant feeding practices, with associated public health harms. We consider how allergy professionals in India can ensure that their clinical and research practice fully supports all aspects of child health and development including optimal nutrition and feeding practice.

Key messages

- One quarter of children are born in India, where ~70% are breastfed for ≥2 years
- Allergy practice in other countries has encouraged specialised formula overuse and contributed to undermining breastfeeding
- Allergy guidelines and formula-sponsored education carry nutrition and health risks for Indian mothers and infants

2 | HISTORY OF INFANT FEEDING IN INDIA

The significance of breastfeeding has been recognised in various depictions of science, mythology, philosophy, art and religion in India. The ancient Indian scriptures of Vedas and Ayurveda describe the breast as 'a pitcher full of nectar' and consider breast milk to have vivifying power. Modern scientific evidence shows an association between breastfeeding and decreased risk of serious childhood morbidity and mortality.[1] Improved sanitation, nutrition and health care in India has resulted in a decline in under-5 mortality from 210 per 1000 live births in 1970 to 32 per 1000 live births in 2020.[8,9] However, India is yet to reach the proposed United Nations Sustainable Development Goals target of under-5 mortality <25 per 1000 live births.[8,9] In addition, high levels of stunting exist among children in India, reflective of malnutrition, though this has also improved over the last 2 decades.[9–11] Policies and programmes that protect, promote and support optimum feeding practices are one of the major strategies to reduce infant and childhood morbidity and mortality.[11,12]

2.1 | Recommendations for breastfeeding in India

The Government of India recommends initiation of breastfeeding within 1 h of birth, exclusive breastfeeding for the first 6 months of life and continued breastfeeding until 2 years of age or beyond along with appropriate complementary feeding.[13] This is aligned with

World Health Organization (WHO) recommendations.[14,15] Although most children in India are breastfed for at least 2 years, only just over half fully adhere to these recommendations, despite the clear benefits for health, development and survival.[1,9,16] The human cost of not breastfeeding all infants and young children as per Government/WHO recommendations in India is estimated at almost 100,000 preventable child deaths and just over 11,000 preventable maternal deaths each year.[17] Financial costs are estimated at $14.5 billion USD per annum, which includes >$100 million USD on treatment for health conditions such as child diarrhoea and pneumonia, partly preventable through breastfeeding promotion.[17,18]

2.2 | Current status of breastfeeding in India

A trend of improved rates of early initiation, exclusive breastfeeding and total breastfeeding duration has been observed in India since the 1990s, with rates higher than most high-income countries, and median breastfeeding duration over 2.5 years in 2019 (Table 1).[9,19] Prior to 1990s, breastfeeding rates had declined and formula feeding increased, due to social changes and formula marketing.[20] The Baby-Friendly Hospital Initiative (BFHI) was launched by WHO and United Nations Children's Fund in 1991 to support breastfeeding, and was implemented in India in 1993, but monitoring activities ceased in 1998.[21,22] In 2016, the Government of India launched a nationwide breastfeeding promotion programme called 'Mothers' Absolute Affection (MAA)' to promote breastfeeding in healthcare facilities and ensure implementation of WHO's 'Ten Steps to Successful Breastfeeding', which form the cornerstone of BFHI.[23] MAA is however not implemented in private hospitals, where almost half of babies are born.[19]

Although breastfeeding rates far exceed those of China, North America and Europe, there is still room for improvement in India's rates of early initiation, exclusive breastfeeding and continued breastfeeding at age 2 years. For example, the early initiation of breastfeeding rate remained static between 2015 and 2019 at around 40%, suggesting ongoing issues with healthcare system support of mothers during pregnancy and at the time of birth.[9,19] This is a significant issue which leads to unnecessary use of formula. The healthcare system bears responsibility for supporting early breastfeeding within 1 h of birth, but the support of exclusive breastfeeding to 6 months and continued breastfeeding with complementary feeding after 6 months requires multisectoral support. This involves government departments, charities and community groups with responsibilities for health, women, children, labour, disaster management, policy planning and law.

Successful implementation of recommended interventions depends on good governance and adequate funding. The World Breastfeeding Trends Initiative report on India assessed 10 indicators of policy and programming, and identified shortcomings in the coordination of policies and implementation of the BFHI, as well as infant feeding practices during emergencies.[24] Overall, India ranked 79 out of 98 countries analysed on breastfeeding policy and support due to insufficient investment in this area, in particular inadequate support for breastfeeding women within the healthcare system.[24,25] Thus, the relatively high level of normative breastfeeding practice in India is fragile and vulnerable, due to weak policy and healthcare system support for breastfeeding women.

2.3 | Trends in formula milk sales in India

One of the major impediments to breastfeeding is the aggressive, poorly regulated promotion of infant formula by the breast milk substitute (formula) industry.[26] In low-middle income countries, widespread aggressive marketing of breast milk substitutes has been associated with increased child morbidity and mortality.[27,28] Despite the WHO International Code of marketing of breast milk substitutes (1981), subsequent World Health Assembly resolutions (1986–2016) and the Innocenti declaration (1990 and 2005) to protect, promote and support breastfeeding, the formula industry uses their significant financial resources to persuade mothers and healthcare professionals to adopt and practice alternate feeding.[27,28] The Parliament of India enacted the 'Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992' (the IMS Act) to curb promotion of commercial baby foods for the consumption of children under 2 and this has successfully constrained sales of formula in India despite reported violations (Table 2).[26]

From 2008 to 2020, milk formula sales in India remained static at around 30,000 tonnes per annum, which compares favourably with other large lower middle income countries such as China and

TABLE 1 Trends in national infant feeding practice for India.

	1992	1998	2005	2015	2019
Initiation of breastfeeding within 1 h (%)	9.5	15.8	24.5	41.5	41.4
Median exclusive breastfeeding duration (months)	1.4	1.9	2.0	2.9	3.9
Exclusive breastfeeding 0–5 months (%)	43.1	46.5	46.4	55.0	63.7
Continued breastfeeding 20–23 months (%)	66.6	68.9	72.8	71.6	73.2
Median total breastfeeding duration (months)	24.4	25.4	24.4	29.6	32.1

Note: Data shown are sourced from the National Family Health Surveys.[19] For continued breastfeeding at 20–23 months in 2005, 2015 and 2019, data are sourced from UNICEF Coverage Evaluation Surveys.[9]

TABLE 2 Infant formula milk sales from 2008 to 2020 in India, China and Brazil.

	Volume of formula milk sold (tonnes)												
	2008	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
India													
Total	30,651	21,730	22,392	23,352	24,126	24,850	25,522	26,206	27,082	27,902	28,701	29,669	29,825
Standard	19,059	9807	10,102	10,492	10,843	11,145	11,422	11,672	11,850	11,986	12,090	11,991	11,582
Follow-on	9094	9356	9642	9998	10,326	10,654	10,955	11,299	11,772	12,216	12,649	13,456	13,982
Toddler	2125	2183	2241	2430	2503	2576	2649	2718	2920	3137	3378	3616	3619
Specialised	374	385	407	431	454	475	496	517	542	562	584	606	642
China													
Total	220,066	258,762	304,481	352,284	407,903	472,969	533,839	557,544	587,409	622,255	653,255	660,480	652,180
Standard	55,981	67,839	79,898	90,952	102,701	116,046	130,072	134,759	142,575	151,842	158,220	153,950	145,670
Follow-on	72,910	82,441	94,347	106,170	119,179	134,004	149,481	151,754	160,253	169,547	177,180	174,170	166,480
Toddler	90,676	107,872	129,476	153,441	182,343	217,079	246,126	261,521	273,551	288,049	302,740	315,460	321,620
Specialised	500	610	760	1720	3680	5840	8160	9510	11,030	12,817	15,115	16,900	18,410
Brazil													
Total	16,640	21,080	27,900	31,540	34,440	37,470	40,890	43,222	44,165	43,294	42,773	42,751	43,508
Standard	4510	5970	8160	9300	10,250	11,190	12,020	12,854	13,164	12,884	12,754	13,060	12,903
Follow-on	3230	4160	5590	6300	6810	7350	7900	8365	8530	8390	8220	8293	8340
Toddler	8760	10,730	13,810	15,470	16,610	17,750	19,020	20,093	20,521	20,010	19,880	19,560	20,504
Specialised	140	220	340	470	770	1180	1950	1910	1950	2010	1920	1839	1762

Source: Euromonitor International from official statistics, trade associations, trade press, company research, store checks, trade interviews and trade sources.[29]

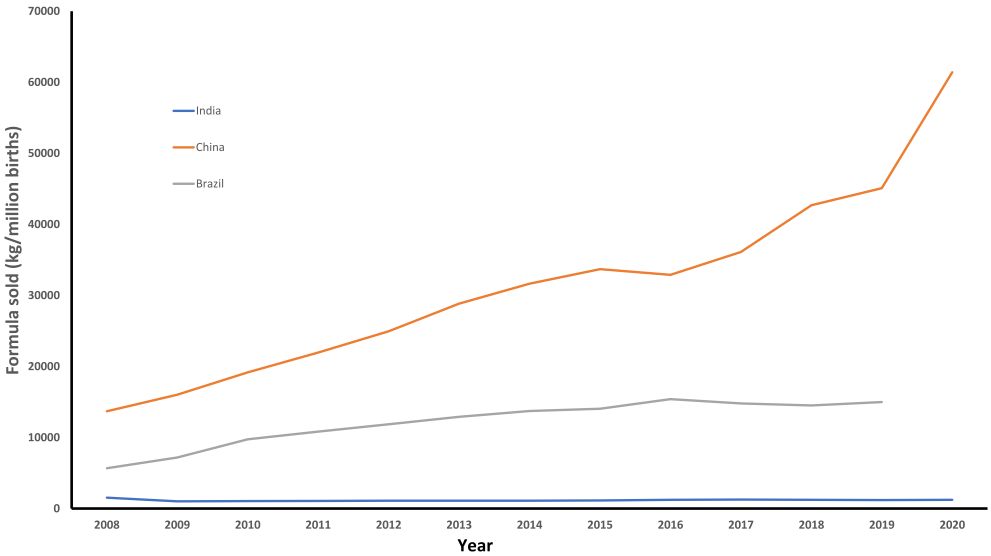


FIGURE 1 Volume of formula milk sales per million births in India, China and Brazil, 2008–2021. Data for formula volumes were sourced from Euromonitor International, which summarises data from official statistics, trade associations, trade press, company research, store checks, trade interviews and trade sources.[29] Data for annual birth numbers were sourced from Indiastat, National Bureau of Statistics of China, Sistema de Informações sobre Nascidos Vivos (SINASC) and Instituto Brasileiro de Geografia e Estatística.[97–99]

Brazil, where consumption almost trebled over the same period.[29] In China, where there has been a significant decline in birth rate, these volumes reflect an even sharper rise in formula sales per live birth (Figure 1).[29] Despite these reassuring Indian statistics, there is evidence that the formula industry continues to violate the IMS Act. A recent WHO report demonstrated the marketing tactics adopted by the formula industry, including personalised social media content that is often not recognisable as advertising.[30] Retail websites, Twitter and Youtube, were the most frequently used platforms in India, and influencers were used on social media to target new mothers, with mothers often receiving contacts on multiple occasions per day to influence their infant feeding decisions.[26,30]

2.4 | Breastfeeding promotion network of India

Breastfeeding promotion network of India (BPNI) is a registered, independent, non-profit, national organisation formed in 1991 to protect, promote and support breastfeeding and appropriate complementary feeding of infants and young children.[31] BPNI has been officially monitoring and implementing IMS Act since 1995.[31] BPNI coordinates the education and training of infant feeding counsellors as a sustainable support to mother–baby dyads.[31] Since 2016, the MAA programme requires adherence to the IMS act. BPNI provides technical help towards scaling up implementation of MAA programme.[32] Aggressive marketing and promotion of infant formula in hospitals affect breastfeeding success.[26,31] The BPNI continues to challenge unnecessary formula use in hospitals by calling for mandatory action for doctors to educate new parents about the benefits of breastfeeding and breast milk and insisting that parental consent is obtained before formula is given to their baby.[32]

3 | RECENT TRENDS IN ALLERGY IN INDIA

There is limited information available regarding trends in allergic disease prevalence in India, with the most comprehensive information arising from the International Study of Asthma and Allergies in Childhood (ISAAC; Figure 2).[33,34] In India, a rise in reported allergic rhinoconjunctivitis was more apparent in adolescents than younger children over an average 7-year interval between ISAAC Phase One and ISAAC Phase Three, while the prevalence of eczema remained relatively stable over the same period.[3,33–37] Previously the incidence of asthma was reported to more than triple between 1979 and 1999 in a study of 20,000 children at one hospital in Bengaluru, Southern India.[38]

A more recent regional study in Bengaluru also reported a possible increase in childhood asthma, but consistent, national-level data to support this are lacking.[3,39] Phase Three of the ISAAC study reported current wheeze in approximately 7% of Indian children aged 6–7 years and 13–14 years, with more than half suffering severe asthma in both age cohorts.[35] Recent data suggest that asthma rates in India remain relatively low by international standards, and stable (reference doi.org/10.1016/S0140-6736(21)01450-1). Rhinoconjunctivitis affected 4.5% of male and 3.8% of female children aged 6–7 years, with higher prevalence among 13–14 year olds (11.7% males, 9.7% females).[36,40] Eczema occurred in 3% of Indian children aged 6–7 years with a similar rate among 13–14 year olds (4.4% male, 3.2% female), and recent data suggest these figures are stable.[37,40,41] India has a lower

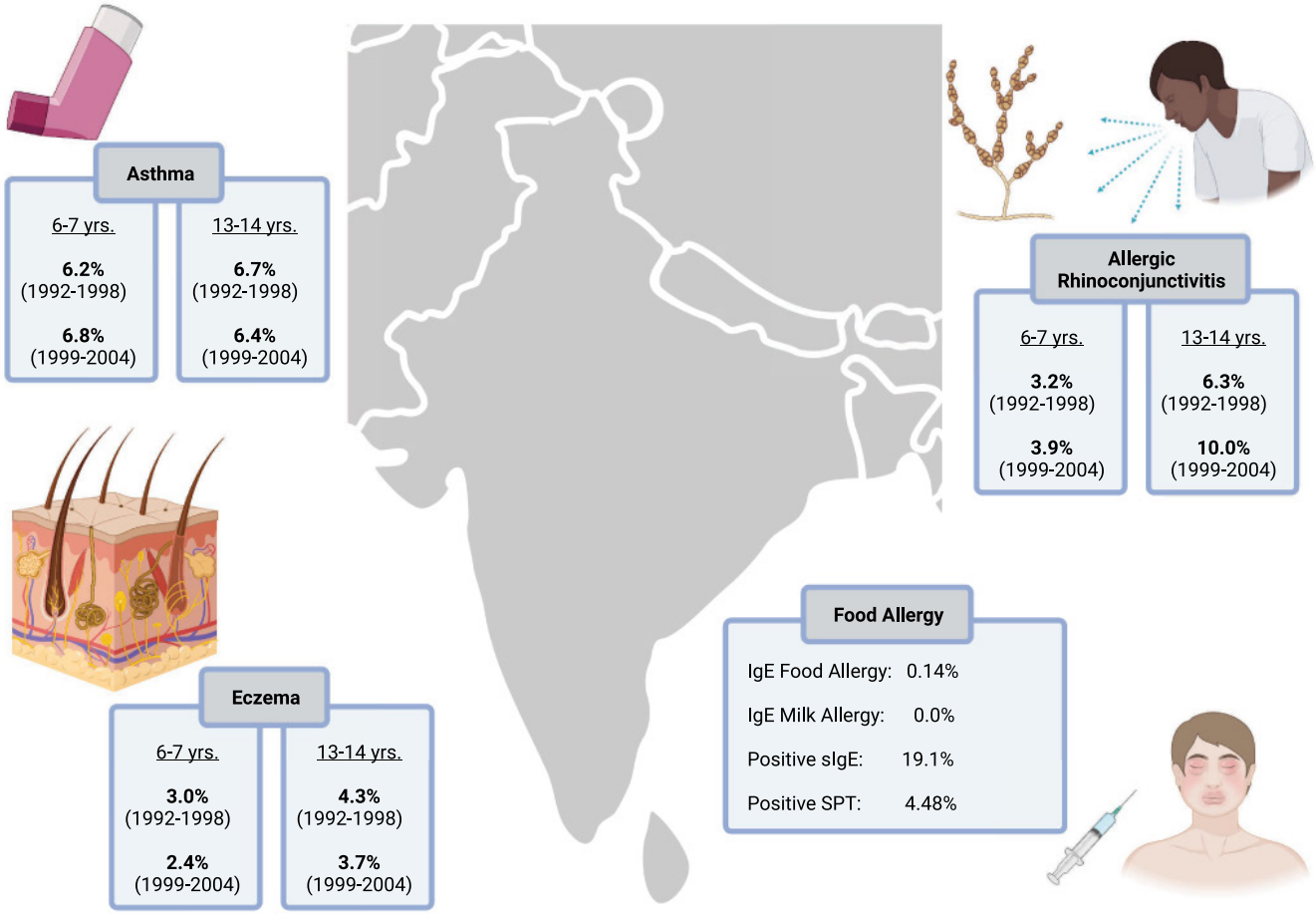


FIGURE 2 Prevalence of allergic diseases in India. Prevalence of asthma, allergic rhinoconjunctivitis and eczema as reported in the Phase One and Phase Three ISAAC studies.[33] Prevalence of food allergy as reported in the EuroPrevall-INCO study.[43] Figure created with Biorender.com.

incidence of paediatric asthma, rhinoconjunctivitis and eczema when compared with Europe, the Americas, Australasia and Africa, but significant regional variation exists.[39,42]

Reliable data on the true prevalence of anaphylaxis in India are lacking.[39] Food allergy appears to be much less common than in high-income countries, with IgE-mediated food allergy affecting 0.14% of Indian children and 1.2% of adults, and peanut allergy affecting <0.1% of young children.[43,44] In contrast with these low rates of food allergy, there are high rates of food sensitisation (children 19%, adults 26.5%).[43,44] Very little epidemiological data exist on prevalence of milk allergy in India. A survey of 5677 children located in two cities representing a cosmopolitan and traditional population found a low rate of parental reported food allergic reaction (1.8%).[43,45] None of the 82 children further evaluated were considered allergic to milk, but milk sensitisation was present in small numbers on both SPT (1.35%) and sIgE testing (2.1%).[43,45]

Overall, there is a low prevalence of allergic disease in India by international standards, data to support an ongoing increase in prevalence are limited, but the absolute numbers of individuals affected by allergic diseases are large due to the high population.[3,33–37]

3.1 | Management of allergy in India

Although the proportion of India's population affected by allergy is low, for some conditions the burden of disease is high.[39] India is home to one fifth of the world population and approximately 37 million asthmatics.[39,46] Outdoor and indoor air quality in India is poor with over three quarters of the population and almost all children under 5 years old exposed to annual weighted mean matter pollution (PM2.5) exceeding World Health Organization recommended limits.[46–48] Contributory factors include industrialisation, traffic pollution, domestic use of solid fuels, mosquito coils and tobacco smoke.[39,49] Asthma management in India is characterised by excessive oral steroid use, lack of confidence in and compliance with inhaled therapies and high levels of sickness absence.[50,51]

The burden of allergic disease is compounded by a paucity of specialised allergy services. Allergy as a distinct medical specialty does not exist in India, undergraduate allergy medical education is limited and <1000 physicians have completed postgraduate educational programmes.[2,39,52] Limited understanding of allergic conditions, cultural beliefs and an underfunded healthcare system where the majority pay for health care prevent many patients accessing adequate advice and treatment for allergic conditions.[2,39,52] Poor access to diagnostics

such as skin prick testing (SPT) and serum IgE (sIgE) impedes accurate diagnosis.[39,52] Adrenaline autoinjectors are not available in India and biological treatment for managing asthma is cost prohibitive.[39,52]

4 | INTERSECTION BETWEEN ALLERGY AND INFANT FEEDING

4.1 | The hydrolysed formula story

There is an important interaction between the two separate issues of improving access to allergy diagnostics and treatments for people affected by allergy; and unintentional promotion of commercial formula milk which undermines the health and well-being of the mother–infant dyad. Here, we illustrate that interaction by discussing two examples of areas where the international allergy community appears to have been co-opted by formula marketing, leading to misleading allergy-based recommendations for infant feeding.

First, the claims that hydrolysed formula could be used to prevent infants from developing eczema or cow's milk allergy. Hydrolysed formula first became available in the 1940s, and in the 1980s investigators considered its use in healthy infants for preventing allergy.[53] They developed the hypothesis that ingestion of hydrolysed proteins in formula would reduce sensitisation to cow's milk, preventing conditions such as cow's milk allergy and atopic eczema.[54] Preliminary studies in the late 1980s and early 1990s suggested hydrolysed formula might have advantages for allergy prevention.[53,55,56] One influential study in 1989, by Dr Ranjit Chandra, confirmed that allergen avoidance in the maternal diet and through use of hydrolysed formula prevented atopic eczema.[56] Retraction of this study, amid concerns of fabricated results, did not occur until 2015 despite a television documentary in 2006 alleging scientific fraud.[57]

These early studies informed a 1991 European Report of the Scientific Committee for Food and statements from European gastroenterology and allergy societies, concluding that hypoallergenic formula was protective against allergy in children at high risk of atopy.[54,58] Infant formula manufacturers' close relationships with paediatricians helped disseminate the allergy prevention concept through professional meetings.[59] Validation of the findings came from an independent Cochrane review, which used both the fraudulent Chandra studies and the German Infant Nutrition Intervention (GINI) study of partially and extensively hydrolysed formula, to support the effectiveness of this strategy.[60,61] In the GINI study, per protocol analyses were selectively reported, showing favourable findings.[61,62] However, intention to treat analyses did not confirm a favourable effect, and other studies published subsequently have also failed to support the effectiveness of hydrolysed formula for preventing eczema or cow's milk allergy.[61–64]

The fabrication and selective reporting of results, combined with close educational and research partnerships between formula companies and allergy professionals, led to widespread acceptance by the allergy community that hydrolysed formula prevented allergy for several decades.[65] Guidelines from Europe, North America, Japan and Australasia no longer recommend hydrolysed formula to prevent allergy or eczema, based on an understanding that there is little credible evidence to support this intervention.[66–69]

This case study illustrates how commercial marketing activities are likely to have undermined efforts to promote breastfeeding by falsely ascribing special properties to hydrolysed formula, and are likely to have induced families to pay a premium for a product with misleading claims.[70]

4.2 | Overdiagnosis and overtreatment of infant milk allergy

A second case study which illustrates the harm that can arise from overpromotion of allergy, facilitated by commercial partnerships with the formula industry, is infant milk allergy overdiagnosis. In high-income countries, there is now up to 10-fold excessive use of specialised formula to treat milk allergy, accounting for 7.6% of US formula sales.[4,71] In both England and Brazil, parent-reported milk allergy was also 10-fold higher than true allergy.[4,72,73] There is evidence that formula industry marketing has played an important role in reframing normal infant symptoms as possible milk allergy, though wider changes in cultural attitudes to health and overdiagnosis of food allergy as a whole may also be relevant.[6,74–76] Through several decades of close partnerships between the formula industry and allergy professionals in high-income countries, milk allergy overdiagnosis has become widely promoted in guidelines.[6] For example, constipation was considered a sign of non-IgE milk allergy in a recent survey of all 70 United Kingdom primary care milk allergy guidelines, whereas an independent expert consensus group did not view constipation as a typical symptom of milk allergy.[77,78] There is significant potential commercial gain in pathologising normal symptoms as milk allergy and formula industry funding of guidelines and educational events reflects this.[6,76,78] A recent analysis of one milk allergy guideline disseminated by formula companies found recommendations labelled 74% of healthy infants as having symptoms of milk allergy.[79] A common recommendation in such guidelines is for breastfeeding women to restrict their diet, a practice which has little or no empirical evidence base and can undermine breastfeeding confidence.[80] As shown in Figure 3, milk allergy overdiagnosis can harm both children and mothers and carries a significant financial burden.

5 | MANAGEMENT OF COW'S MILK ALLERGY IN INDIA: PROBLEMATIC GUIDANCE

Characterising the presentation of milk allergy in India is hampered by very low rates of milk allergy in epidemiological studies, with consequent low levels of awareness and concern and diagnostic activity around milk allergy.[39,48,52] Guidelines rely on European data and

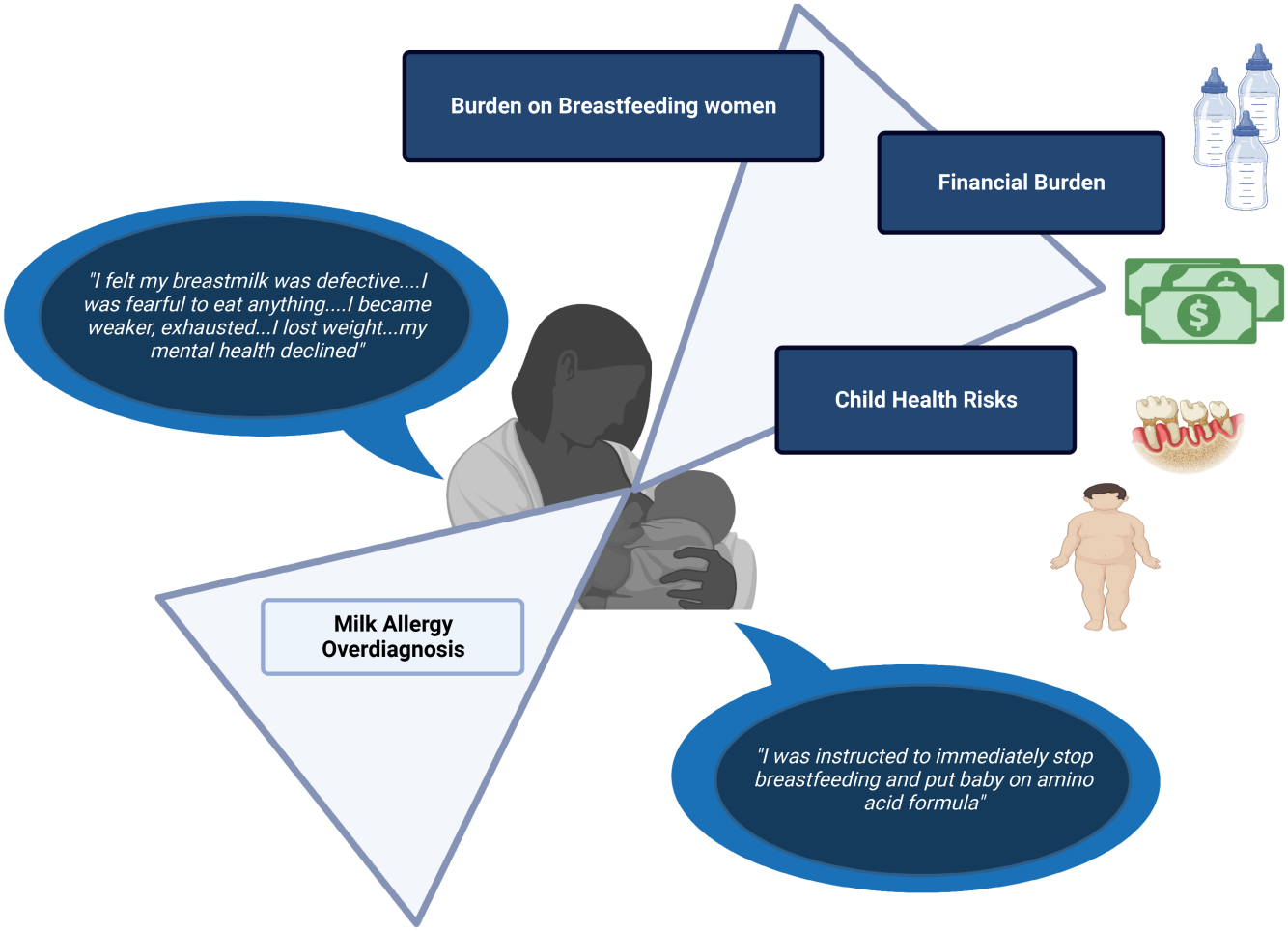


FIGURE 3 Harms of milk allergy overdiagnosis. Adverse impacts of milk allergy overdiagnosis include specialised formula costs for families and healthcare systems and added costs of other dairy-free alternative foods.[4,100] Child health risks include less healthy carbohydrate sources in place of lactose in specialised formula, health and nutrition risks associated with formula use in place of breastfeeding or associated with other non-dairy foods such as plant milks and increased risk of developing milk or other food allergies due to exclusion of food allergens from child's diet.[15,100–107] The burden on breastfeeding women includes unnecessary dietary restriction affecting quality of life, mental health and nutrition; reduced breastfeeding confidence and reduced duration of exclusive or total breastfeeding affecting maternal physical and mental health.[7,78,80] Figure created with Biorender.com.

mirror Western practice, especially that of the international paediatric gastroenterology community, which may not be appropriate given the apparent rarity of milk allergy in India.[48,58,81,82] Some Indian studies have implicated milk allergy in malabsorption syndromes in young children presenting with chronic diarrhoea.[81,83–85] The 2020 Indian Academy of Pediatrics/Indian Society of Pediatric Gastroenterology, Hepatology and Nutrition milk allergy guideline is the first national guideline for milk allergy diagnosis and management in India.[81] Recommendations are largely derived from guidelines used in high-income countries, with interpretation for local context. For example, partly due to limited accessibility of diagnostics in India, the guideline does not recommend relying on specific IgE testing, but suggests using dietary exclusion and reintroduction for diagnosis. Review of the guideline recommendations appears to support the hypothesis that professionals managing allergy or possible allergy in India may undermine normative breastfeeding practice through their recommendations.

A comparison between the 2020 Indian milk allergy guideline recommendations and national infant and young child feeding guidelines is shown in Figure 4. The guideline appears to contradict national guidance for promoting, protecting and supporting breastfeeding in India. For example, the milk allergy guideline advises breastfeeding for at least 6 months, which is at odds with traditional infant feeding practice in India where breastfeeding commonly continues for the first 2–3 years of life, as per national and international recommendations.[13–15] Although this is an Indian guideline on milk allergy, it is more reflective of medical practice in high-income countries, which often emphasises breastfeeding until 6 months old and overlooks recommendations to continue breastfeeding to at least 2 years. This partly reflects low rates of breastfeeding beyond 6 months in high-income countries, but is likely also influenced by the sponsorship of guideline development, allergy academies and guideline authors by the formula industry.[5,6,76] The prominence of advice for mothers of exclusively

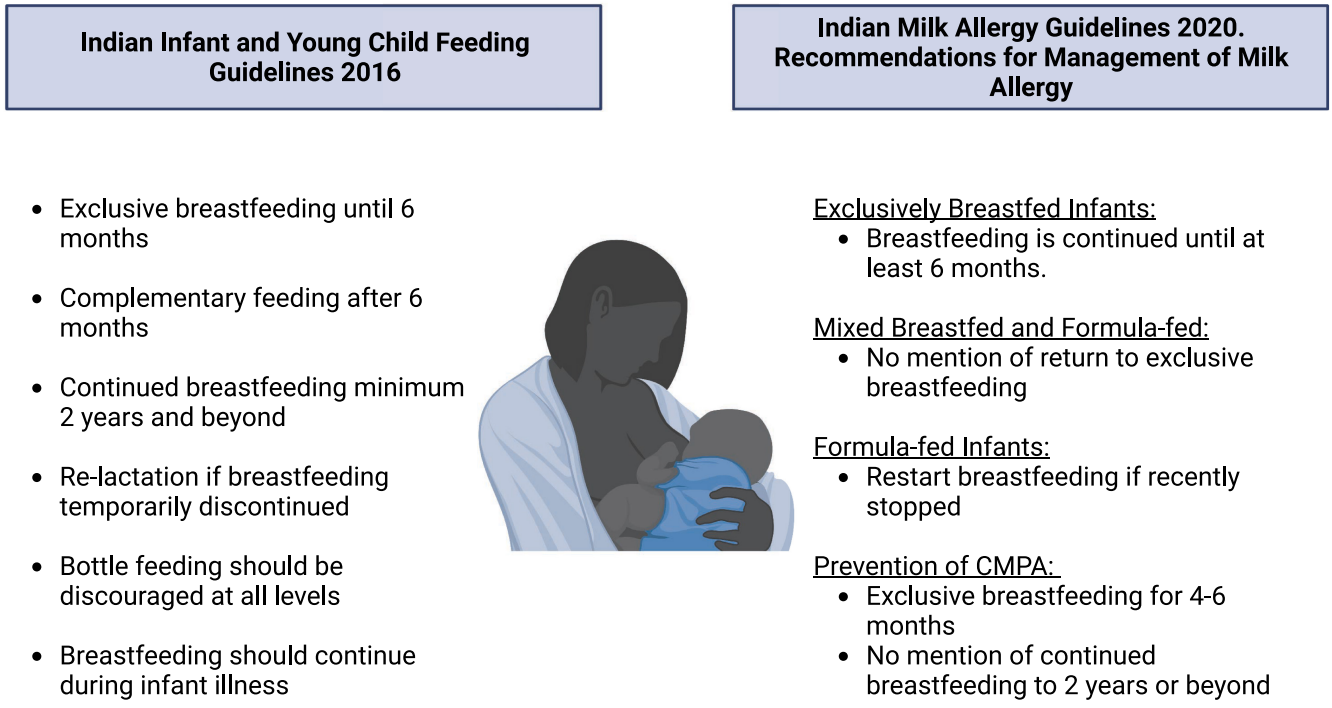


FIGURE 4 Comparison of breastfeeding recommendations in the national feeding guidelines and milk allergy guidelines. Recommendations are summarised from the Indian Infant and Young Child Feeding Guidelines 2016[14] and Indian Guidelines on the Diagnosis and Management of Cow's Milk Protein Allergy (CMPA).[81] Figure created with Biorender.com.

breastfed infants to eliminate all dairy and related foods in the 2020 Indian milk allergy guideline suggests the guideline recommendations could undermine breastfeeding confidence and adversely affect quality of life in breastfeeding women.[81]

A recent independent Delphi consensus study identified very few clinical scenarios where consensus could be reached that advising restricted maternal diet during breastfeeding is good clinical practice.[78] Authors noted that such advice can place a significant burden on breastfeeding women and, through premature cessation of breastfeeding, their children.[7] While the 2020 Indian milk allergy guideline recommends re-commencing breastfeeding, if possible, for the management of milk allergy in formula-fed children, a similar emphasis on breastfeeding without formula supplementation is not made for children who are mixed fed.[81] The 2020 Indian milk allergy guideline recommends using partially hydrolysed formula for milk allergy prevention, despite this being rejected by the international allergy community in recent years.[81,86,87] Table 3 shows the key areas of discrepancy between this first Indian milk allergy guideline and the recent independent Delphi consensus.

6 | FUTURE RISKS FOR INFANT FEEDING RELATED TO DEVELOPMENTS IN ALLERGY SCIENCE

In recent years, the allergy community have shifted the focus of allergy prevention efforts to tolerance induction.[88] There is therefore increased pressure within the field of allergy that solid food introduction should occur earlier than 6 months old, in order to allow earlier allergenic food introduction to reduce risk of food allergy.[89] Currently WHO recommends exclusive breastfeeding for the first 6 months.[15] Yet commercial dietary products containing allergenic food for infants aged under 6 months are increasingly marketed in high-income countries. Promotion of early dietary interventions to prevent the development of food allergies may therefore directly undermine WHO recommendations for optimal infant feeding.[90] This is a particular concern in India, where food allergy is very uncommon and adverse health consequences of shortened breastfeeding duration can be severe.

The issue of hydrolysed formula for allergy prevention has been constrained at a regional level by a European Directive prohibiting health claims for hydrolysed formula products.[15,91] However, there is provision within the Directive for future claims of milk allergy prevention being included in labelling of these products, if these can be appropriately substantiated.[15,91] The message of allergy prevention being important in child nutrition can be exploited by promotional activities which co-opt the allergy community and undermine breastfeeding. Where India-specific scientific data and practice guidance are limited, reliance on evidence and guidance from high-income countries with low breastfeeding rates may lead to nutritional interventions that conflict with India's normative infant feeding practice. Excessive focus on allergy may also interfere with the recognition and management of other infant health issues such as infectious gastroenteritis, malrotation and immune deficiency.[76,77,79,92]

TABLE 3 Comparison of Indian Milk Allergy Guideline recommendations with international Delphi consensus study on diagnosis and management of milk allergy.

	Indian Guideline, 2020	Delphi Consensus, 2022	Key problems with Indian Guideline Recommendation
Diagnosis of CMA in exclusively breastfed infant	Maternal dietary elimination for 2 weeks for non-IgE symptoms and 4 weeks for atopic dermatitis or allergic colitis	Consider milk allergy and maternal dietary elimination only if chronic symptoms with faltering growth and protein-losing enteropathy	Maternal dietary eliminations have been shown to affect maternal health and may undermine breastfeeding[7,76]
Management of CMA in exclusively breastfed infant	Maternal dietary elimination of bovine milk and all dairy products	Maternal dietary elimination unnecessary	Milk allergic reactions through breast milk are unlikely[80] Unnecessary maternal dietary elimination risks adverse effects on maternal well-being and undermining breastfeeding[7]
Management of CMA in mixed breast and formula-fed infants	Continue breastfeeding with extensively hydrolysed formula <6 months old or soya formula >6 months old	Support continued breastfeeding without use of breast milk substitutes (exclusive breastfeeding to around 6 months and continued to 2 years or beyond)	Use of formula undermines breastfeeding and contradicts Indian and World Health Organization feeding guidelines[14,15]
Prevention of CMA	Exclusive breastfeeding for 4–6 months Partially hydrolysed formula if family history of allergy in both parents and exclusive breastfeeding not possible	Initiation of specialised formula should not be advised for preventing milk allergy or other atopic conditions, even in infants with a family history of allergy	Attributing unscientific properties to specialised formula[87]

Note: Summary of recommendations from the 2020 Indian Academy of Pediatrics/Indian Society of Pediatric Gastroenterology, Hepatology and Nutrition milk allergy guideline.[81] Comparison is made with independent consensus-based guidance undertaken by international experts with no conflict of interest in relation to the formula industry.[78]

BOX 1 Allergy practice which can potentially undermine child health.

- Formula industry sponsorship of allergy education or guideline development.
- Allergy diagnosis based on allergy testing without careful consideration of clinical history.
- Recommendations to use specific formula products for allergy prevention.
- Recommendations for breastfeeding women to restrict their diet.
- Diagnosis of milk allergy in infants with no reproducible symptoms related to cow's milk protein ingestion.

7 | RECOMMENDATIONS FOR BEST ALLERGY PRACTICE IN INDIA

Disparities exist between the first Indian milk allergy guideline, which is based largely on the recommendations from high-income countries with low breastfeeding rates, and the national recommendations for optimal early childhood feeding practice (Figure 4).[13,81,86] This suggests that the first steps have already been taken along a path where clinical allergy practice serves to undermine breastfeeding and other aspects of normal infant care. Food allergy is rare in India. Food sensitisation rates, however, are high and it is plausible that increases in use of allergy diagnostics may lead to overdiagnosis of allergic disease without appropriate clinical interpretation.

A recent systematic review found little evidence for maternal dietary elimination of dairy in the routine management of breastfed infants with milk allergy.[80] In a country where malnutrition in women and children is common,[11] care must be taken not to interfere with optimal nutrition when managing medical conditions.

Best allergy practice in India should include a focus on avoiding overdiagnosis of food allergy in infants,[77,79] preventing unnecessary maternal dietary eliminations which can negatively impact maternal health and undermine breastfeeding,[7] and ensuring the use of specialised low-allergy formula products is limited to confirmed milk allergy when breastfeeding or other forms of breast milk feeding are not possible.[4,78] Recent recommendations from an international, non-conflicted, multi-disciplinary panel of experts may be useful to clinicians in India with limited resources.[78] Concern has been raised regarding relationships between allergy professionals and the formula industry, and WHO recommends that healthcare professionals should avoid conflicts of interest with the formula industry.[6] Box 1 outlines allergy practice which can adversely affect infant feeding based on the European experience and should be avoided.

The Indian milk allergy guideline declares no funding, and competing interests are not stated.[81] However, it includes recommendations from a European milk allergy guideline where

conflicts of interest with formula industry have been declared by the majority of authors.[78,82] It is worthwhile noting that other regions of the world with a breastfeeding culture are affected by many of the issues discussed in this article. For example, in South Africa the formula industry sponsors allergy societies and allergy education initiatives. These include an Allergy in Africa webinar series with potential to drive allergy overdiagnosis on the African continent and foster clinical practices which undermine breastfeeding.[93]

8 | CONCLUSIONS

There is a risk that the development of allergy as a specialty and increased awareness and concern about allergies in India could undermine breastfeeding, carrying health and nutrition risks for one quarter of the world's children. To mitigate against this risk, it is important that all healthcare professionals dealing with infants and young children, including allergy practitioners, maintain independence from the formula industry to avoid unconscious influences on prescribing habits.[6,94–96] Milk allergy guidance produced without formula industry influence produces recommendations that are more supportive of breastfeeding women and awareness of this is important for future guideline development. If conflicts of interest exist between allergy practitioners and the formula industry in India, there is a risk of significant harm to the world's children through facilitation of formula milk marketing.[78]

AUTHOR CONTRIBUTIONS

Boyle contributed to the concept and design of the study. Allen, Gupta, Mundell, Gupta, Thakur, Nagarajan and Boyle drafted the article. All authors critically revised the manuscript and provided administrative, technical or material support.

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CONFLICT OF INTEREST STATEMENT

RJB declares consultancy payment from Cochrane, John Wiley and sons and the British Society for Allergy and Clinical Immunology for editorial work, and payment for expert witness work in cases involving food anaphylaxis and a disputed infant formula health claim. AG is employed by the Breastfeeding Promotion Network of India. PB is supported by a Future Fellowship award funded by the Australian Research Council (project number FT220100690). All other authors declare no conflicts of interest in relation to this article.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

ORCID

Alexandra Mundell https://orcid.org/0000-0003-1177-7336
Robert Boyle https://orcid.org/0000-0002-4913-7580

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