Enforcing the International Code of Marketing of Breast-milk Substitutes for Better Promotion of Exclusive Breastfeeding: Can Lessons Be Learned?

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Abstract

Exclusive breastfeeding, one of the best natural resources, needs protection and promotion. The International Code of Marketing of Breast-milk Substitutes (the Code), which aims to prevent the undermining of breastfeeding by formula advertising, faces implementation challenges. We reviewed frequently overlooked challenges and obstacles that the Code is facing worldwide, but particularly in Southeast Asia. Drawing lessons from various countries where we work, and following the example of successful public health interventions, we discussed legislation, enforcement, and experiences that are needed to successfully implement the Code. Successful holistic approaches that have strengthened the Code need to be scaled up. Community-based actions and peer-to-peer promotions have proved successful. Legislation without stringent enforcement and sufficient penalties is ineffective. The public needs education about the benefits and ways and means to support breastfeeding. It is crucial to combine strong political commitment and leadership with strict national regulations, definitions, and enforcement. National breastfeeding committees, with the authority to improve regulations, investigate violations, and enforce the laws, must be established. Systematic monitoring and reporting are needed to identify companies, individuals, intermediaries, and practices that infringe on the Code. Penalizing violators is crucial. Managers of multinational companies must be held accountable for international violations, and international legislative enforcement needs to be established. Further measures should include improved regulations to protect the breastfeeding mother: large-scale education campaigns; strong penalties for Code violators; exclusion of the formula industry from nutrition, education, and policy roles; supportive legal networks; and independent research of interventions supporting breastfeeding.

Keywords

advance, Asia, ban, boycott, breastfeeding, breast-milk substitute, Code, enforcements, follow up, formula, infant feeding, Laos, laws, malnutrition, policy, regulations, violations

Background

Despite some improvements over the past 2 decades, undernutrition remains the major cause of child deaths worldwide (45% of 3.1 million deaths annually).1 Efforts to improve infant feeding policies and practices continue to be challenging issues in global health care.2 Worldwide, 0.8 million infant lives could be saved each year by improved breastfeeding alone.1 Although exclusive breastfeeding (EBF) remains one of the cheapest and best practices to protect infants’ and mothers’ lives,2-4 effective support for EBF is often lacking and, globally, EBF rates vary widely (Figure 1).5 Disparities in EBF rates are particularly high in low- and middle-income countries (LMIC).

The use of formula milk by poor families is a significant financial burden, and in practice, overdilution and use of unsafe water sources often result in malnutrition and disease.7-11 The World Health Assembly (WHA) target...
is that by 2025, 50% of infants should be exclusively breastfed for the first 6 months of life.\textsuperscript{10}

Exclusive breastfeeding is a natural resource, universally available but especially endangered in LMIC by the practices and promotions of the formula industry.\textsuperscript{2,9-12} In these countries in particular, the millions of dollars spent on formula promotion are in sharp contrast to the limited public health support for breastfeeding. In South Asia alone, formula profits are expected to grow 31% by 2015 from the 2011 figure of US$25 billion, associated with significant decreases in breastfeeding rates.\textsuperscript{10} The formula industry claims that breastfeeding is the best choice and states that it promotes infant formula only for mothers unable or unwilling to breastfeed. The paradox of this claim and the formula industry’s financial interest presents a significant conflict of interest.\textsuperscript{9,13} The threat that formula promotion poses to breastfeeding is frequently overlooked in political and scientific discussions. For example, a recent \textit{Lancet} series presented the results of 110 randomized controlled trials on breastfeeding promotion but did not address the specific public health and legal actions that were urgently needed to support and protect mothers, their babies, and EBF from formula promotion.\textsuperscript{1}

In 1981, in reaction to the formula marketing campaigns in LMIC of the late 1970s, the WHA approved the International Code of Marketing of Breast-milk Substitutes (the Code).\textsuperscript{11} Subsequent protective resolutions or amendments have been ratified each year to adapt to the changing practices of formula marketing, breastfeeding, and lifestyles. Formula marketing practices continue to circumvent the Code, and numerous Code violations have been documented over the years.\textsuperscript{12} Only 37 (19%) of the 199 countries reporting to the World Health Organization (WHO) have fully implemented the recommendations.\textsuperscript{5} For example, although Indonesia has one of the strictest regulations, insufficient implementation fails to adequately support EBF.\textsuperscript{14}

Another major barrier for EBF is the lack of regulations and protected breastfeeding areas in offices and factories with working mothers.\textsuperscript{7,10} These barriers to breastfeeding are not insurmountable as evidenced by successful workplace interventions.\textsuperscript{15}

Exclusive breastfeeding reduces health care costs worldwide. According to a cost analysis in 2010,\textsuperscript{16} suboptimal breastfeeding in the United States costs US$13 billion and results in more than 900 deaths annually. An excess of
fatalities, from 933 to 5796 infant deaths per year, and more than US$2 billion in annual costs were attributed to suboptimal breastfeeding in Mexico.17 Paradoxically, nonbreastfed children in developed countries, where the lowest rates of EBF prevail, may be receiving the poorest quality nutrition.

Characteristics of Code Violations in Low- and Middle-Income Countries

In countries with weak or nonexistent legislation, the formula industry is responsible for monitoring and enforcing the Code.11 Frequent violations are reported by independent whistleblowers with little public health response or action.12,14,18,19 As with the tobacco and alcohol industries, formula companies indulge in practices abroad that may be banned or severely restricted in their home countries.6,8-21 Code violations include promotion of formula products to the public, even in health care facilities. Attractive labels and unsubstantiated claims mislead parents into believing that these products improve intelligence and protect children from illness.7,10,12 Sponsorships by formula companies and industry-supported education, health fairs, or scientific conferences are attractive, particularly to health care workers with low incomes and limited education resources.7-10 The formula industry claims to respect the Code and that their advertising targets people who can “afford” or who “need” their products, while they mislead them by insinuating that formula might be the better choice.9,10,12,14,22

Examples from Southeast Asia and Other Countries: Successful Interventions and Their Limitations

The experience in Laos offers illustrations of how the formula industry exploits developing countries in the global search for profits. Laos has traditionally high breastfeeding rates (up to 95%) but low EBF among infants < 6 months of age (26% in 2006) due to the prevalence of traditional postnatal nutrition practices (premasticated glutinous rice, postpartum taboos).23,24

Laos endorsed the Code, and in 2004, the Ministry of Health stopped the spread of billboards advertising formula products in the capital of Vientiane and the southern city of Pakse.20 The Nestlé marketing representative was repeatedly informed by us that their Bear Brand coffee creamer label of a bear suckling its cub was causing confusion among illiterate Lao mothers. Only after the BMJ publication of a national survey and a series of rapid responses, which showed that misleading advertising had severe consequences of malnutrition and death, did Nestlé agree to change its logo.6,18,20-22 After we provided further evidence of deaths in ethnic minority villages, the sale of Bear Brand coffee creamer was discontinued.25 However, the label reappeared on breast milk substitutes (BMS) and advance formula, advertised for feeding toddlers older than 1 year, but in modified versions: a mother bear holding its cub on its lap but not in the breastfeeding position, or holding a glass of milk instead.

Although such promotions may not have been covered by the Code, subtle plays on words or images that often mislead parents into using formula incorrectly are examples of how formula companies circumvent the Code.7

In 2010, UNICEF, together with the Lao health authorities, launched a breastfeeding and Code information campaign. As a result, many serious violations disappeared from health centers and hospitals countrywide, and the EBF rate among infants < 6 months of age increased to 40%.26 However, small cans of sterilized milk depicting a teddy bear with a glass or a cub are still on sale for less than US$1.00 in Laos, Cambodia, Vietnam, the Philippines, Thailand, and other countries.26 Farther away from Southeast Asia, in Germany, the misleading Bear Brand logo with the cub in the breastfeeding position is still widely used on coffee creamer, T-shirts, and other products.27,28

Humanitarian agencies have begun addressing Code violations. In 2011, 19 humanitarian organizations working in Laos refused to apply for a Nestlé grant of US$480 000 offered to support projects in developing countries.28 New Code violations emerged that we described in a systematic report in 2012.26 Violations were primarily related to marketing practices, advertisements, and unsubstantiated claims of improved intelligence and/or immunity with formula use. Claiming to promote nutrition in schools, formula companies intensified promotion of advance formula for preschool children. Overall, targeted scientific investigations, health education programs, awareness campaigns, and legislation effectively support the Code, but success remains fragile and person-dependent. Continuous political commitment and surveillance as well as more detailed laws and penalties will be needed for substantial and sustained protection of breastfeeding.

In Thailand, the EBF rate among infants < 6 months of age is only 15%. The country is a prime example of the effect that unregulated advertising has had on the rate of breastfeeding.4 Promotions for all kinds of formula products are highly visible on billboards, in shops, on television, at medical conferences, and in health care facilities. Although television advertising of formula products is prohibited in neighboring Laos, popular Thai programs, with formula advertisements, are telecast into Lao households in a language understood by Lao mothers. In 2014, Thailand was still debating a draft law based on the Code.29

External politics can interfere with protection of EBF. For example, in Vietnam, where the EBF rate is one of the lowest in the region (17% among infants < 6 months of age),4 the US embassy in Hanoi tried to stop Vietnamese legislators from passing laws protecting breastfeeding.30 This political action contrasts with the US Surgeon General’s Call to Action to Support Breastfeeding, which supports the Code and holds formula marketers accountable for compliance.31
Cambodia has made notable efforts to improve breastfeeding rates. Since the 2004 government prioritization of EBF, diverse activities and health education messages have contributed to a national breastfeeding movement in hospitals and community-based education programs. Subsequently, EBF among infants < 6 months of age rose from 7% in 2000 to 71% in 2010.

Indonesia passed a very strict law with precise penalties for Code violations in 2011, ranging from fines of 100 million rupiah (approximately US$7572.90) to a 1-year prison term. Exclusive breastfeeding rates among infants < 6 months of age increased from 32% in 2007 to 42% in 2012. However, implementation of the law remains poor and formula companies continue to promote BMS.

India has one of the most stringent legislations protecting breastfeeding. The sale of infant formula remains low, but EBF rates (46% among infants < 6 months old) are not increasing, suggesting other challenges. Advertising, gifts or free samples, promoting infant formula to doctors and health professionals, pictures of mothers or babies on labels, the sponsorship of events by formula companies, and donations of education material with formula products are strongly prohibited. The labeling of all baby food products must follow certain criteria and cannot be promoted for children younger than 2 years. However, implementation still remains challenging and continuous vigilance is needed. The Indian Academy of Pediatrics recently boycotted nutrition workshops when industry sponsorship was exposed. Light sentences to companies violating the Code minimize the effectiveness of the strict Indian legislation. Recently, companies were partially excused from flagrant violations on the basis that they had committed only a single “mistake.”

In this context, the example of the Indian state of Assam is of extreme interest. Assam achieved an impressive EBF rate, among infants < 6 months of age, increasing from 29% in 1999 to 63% in 2006 through a coordinated and comprehensive strategy led by the state government in partnership with UNICEF and several nongovernmental organizations. The key intervention was health and nutrition workers actively promoting EBF at village and household levels. Employers were encouraged to facilitate breastfeeding and mothers were advised how to organize and use breast milk exclusively. It is clear that Assam is an example of how proper coordination between the government and the private sector can ensure policies that are in compliance with the Code.

Pakistan provides another example of how positive action can be achieved. In the state of Punjab, new laws regarding the advertising of BMS were passed in August 2014 with immediate effect. As an important step toward implementation of the Code, a dedicated board in the government facilitated the drafting of the legislation. This board has been authorized to recommend investigations of manufacturers, distributors, or health workers if they are reported to be in violation of these laws.

Examples from Other Continents

Malawi, Uganda, and Zambia are 3 good examples of successful EBF promotion. Exclusive breastfeeding among infants < 6 months of age is higher than in surrounding countries: 71% in Malawi, 62% in Uganda, and 61% in Zambia. Promotion of formula products is not visible. The Ugandan Ministry of Health has strong regulations to protect health care workers from conflicts of interest with formula companies, and the Ugandan Pediatric Association does not accept promotions or sponsorships of medical conferences (L. M. Srour, MD, MPH, DTM&H, personal communication, August 2014).

In Turkey, EBF rates have dropped throughout the country. Today, only 1.3% of newborns are exclusively breastfed for the first 6 months. In 2013, a marketing campaign by the Danone formula company used pseudo-scientific calculations online, suggesting that mothers were not providing enough breast milk to meet their infants’ needs. This campaign boosted infant formula sales in Turkey by at least 15% and probably encouraged breastfeeding mothers to switch to formula feeding unnecessarily. Media reports, strong statements by national health professionals, and support from international health organizations including WHO and UNICEF were needed to stop this flagrant Code violation.

Interpretation and Lessons Learned

Lessons from the Formula Industry

The formula industry often has conflicts of interest regarding infant formula promotion. Formula companies try to maintain an honorable façade despite frequent less honorable practices. Chief executives and senior management claim to be fully dedicated to nutrition promotion and to be unaware of Code violations, while their lower management maintains strong pressure on their staff to increase sales. Code violations by formula companies are not “innocent mistakes” and should not be excused, as was done in India recently.

The formula industry repeatedly plays hide-and-seek with Code advocates. To avoid detection, production in 1 country is discontinued, or labeling changed, while such promotions continue in other countries.

Therefore, the formula industry should not be involved in any national or local nutrition education programs or allowed to advise on nutrition and health policies.

Lessons from Effective Interventions

Political will at the highest level is crucial, both for effective legislation and for enforcing the laws. There is evidence that in countries where an authority has the power to draft regulations and monitor and enforce them, compliance with the Code can be successful. Political agreement on the Code must be backed by local regulations and adapted to a country’s specific conditions in order to regulate all individuals acting as
intermediaries in formula promotion (good examples are India, Indonesia, and Pakistan).5,8,14,15,33,36,39

Effective partnerships, focused strategies, and community-based actions can indeed double the rates of EBF in a relatively short time (as demonstrated in the state of Assam).37 Measures must be organized with a concerted and holistic multilevel, multisector approach. There should be various levels of action and education to include the family, the community, health staff, retailers, companies, and local and central governments.10,33,37

Furthermore, large-scale community education to promote breastfeeding and safe feeding practices is needed, particularly to counteract the years of formula promotion. Families, especially young women and adolescent females, must receive adequate education and information to make well-informed infant feeding decisions. This should include education about the inappropriateness of canned milk products (coffee creamer, sweetened milk) as BMS.

Language barriers and illiteracy make poorer and less educated people more vulnerable to the mistaken belief that any processed milk is an appropriate BMS. Deceptive advertising with misleading logos are particularly dangerous for those who are illiterate and cannot afford proper formula. Mothers in urban areas are more at risk than those in rural ones.7

Table 1. Recommendations to Improve Exclusive Breastfeeding (EBF) and Strengthen the Enforcement of the International Code of Marketing of Breast-milk Substitutes (the Code).

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<th>A. Legislation</th>
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<td>1. International law and endorsement (the Code)</td>
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<td>a. International harmonization of legislation</td>
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<td>b. International regulations to impede repetition of Code violations in different countries</td>
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<td>2. Establish international and national panels of dedicated lawyers who develop:</td>
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<tr>
<td>a. Local legislation and regulations, including penalties to be adapted to a country’s conditions</td>
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<td>b. Regulation of advertisement and labels, improving labeling similar to requirements for health warnings on cigarette packages</td>
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<td>c. Laws to protect breastfeeding time for mothers at work and extending maternity leave</td>
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<td>d. A legal network to facilitate rapid detection and reporting of violations to the authorities</td>
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<th>B. Enforcement of law</th>
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<td>3. An international legal mechanism has to be developed to call to account all violators involved including at the highest level internationally.</td>
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<td>4. Legal transparent national system for penalties for Code violations by individuals and responsible staff of formula companies including criminal charges</td>
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<td>5. National EBF committee with legal power to implement EBF protection legislation, receive violation reports, conduct surveys, and ensure the reporting of violators to the appropriate process: trials and conviction of offenders</td>
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<td>6. Continuous violation monitoring system by an independent board and general public/health staff</td>
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<td>7. Denounce and appeal weak judicial decisions, which undermine the credibility of the Code</td>
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<td>8. Ensure widespread media dissemination of trials, violations, etc</td>
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<td>9. Ban companies violating the Code from the national market</td>
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<td>10. Ban formula companies from any kind of education/nutrition responsibility and from any participation in the development of national health policy</td>
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<td>11. Mandatory licensing procedures and education about EBF for formula representatives and sales middlemen conducted by an independent professional team</td>
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<td>12. Identify conflicts of interest and establish an ethical evaluation process for politicians, researchers, health staff, and key stakeholders</td>
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<th>C. Education</th>
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<td>13. Awareness campaigns regarding mothers’ rights and laws to protect and promote breastfeeding</td>
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<td>14. Large-scale community education to promote breastfeeding and safe feeding practices using a multilevel and multisector approach</td>
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<td>15. Education of health staff from university to village level</td>
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<td>16. Empowerment of women/mothers: empowerment of women’s associations with information regarding EBF, peer education teams, etc</td>
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<td>17. Targeted campaigns with special focus on high-risk populations (such as in urban areas, illiterate mothers, etc)</td>
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<th>D. Health research</th>
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<td>18. Mandatory disclosure of all conflicts of interests in any research or expert statements on breastfeeding and formula products</td>
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<td>19. Independent research institute to advise policy makers</td>
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<td>20. Further research on effective interventions to improve and increase EBF</td>
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<th>E. Funding and taxation</th>
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<td>21. Prohibit and penalize any kind of direct donations or incentives that could corrupt health staff, legislation, law enforcement, or health research</td>
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<td>22. Increase taxation of the formula industry for sales above the expected quota of formula feeding</td>
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<tr>
<td>23. Allocate sufficient public funding to support EBF and implementation of the above-described recommendations</td>
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Local actions (such as bans, boycotts, and advocacy) can be successful but have limited effect if they are not integrated into a more global approach.

Regulations are needed to support breastfeeding for working mothers and encourage their employers to allow them time to breastfeed. Alternatives must be found for mothers who migrate to find jobs, leaving their infants in someone else’s care.

Whistleblowers and people resisting formula industry pressures, despite strong financial conflicts of interest, must be protected, including those who facilitate detection of violations and report these to the authorities.

Research and Public Health Perspectives

New ideas are needed to prevent companies from influencing health professionals and researchers. For example, to offset the shortfall of financial support by the formula industry for health staff to attend scientific meetings, the formula industry could be taxed. Alternatively, systematic taxation of formula profits could be used for increased governmental support of EBF promotions through the media and other avenues. However, any action with formula companies should be carefully evaluated, as the industry is eager to be involved in nutrition education for health care workers, which has led to inadvertent promotions of their products and brand names.16

There is a need to accumulate more evidence of sustainable and scaled-up effective interventions.15,32,37 Evidence-based advocacy is needed to increase political will to finally agree on and create an international legal framework for implementation of the Code.32

To conclude with these lessons, we propose a list of recommendations as a starting point for consideration and discussion (Table 1).

Conclusion

Exclusive breastfeeding needs support with public health legislation to protect this valuable natural resource from companies promoting the use of formula. Mothers with limited education and resources are easily misled by deceptive advertising and are more vulnerable to the risks of BMS. The additional expense of BMS compromises their livelihood and the health of their infants. Promotions by formula companies need to be monitored and the industry pressured into complying with the Code in word and deed. Successful experiences and holistic approaches can strengthen the Code and need to be scaled up. Community-based actions and peer-to-peer promotion have been effective. It is crucial to combine strong political commitment and leadership with stringent national regulations, definition of penalties, enforcement of the law, and imposition of penalties for all violators, including formula industry senior management. Protection of exclusive breastfeeding will result in saving infant lives and improving the health of children throughout the world.

Acknowledgments

The authors are grateful to Dr Cindy Chu for her comments on the manuscript.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

References

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27. Bärenmarke [Bear Brand]. http://www.amazon.de/s/ref=nb_sb_noss_2?_mk_de_DE=%C3%85M%C3%85%C5%BD%C3%95%C3%91&url=search-alias%3Daps&field-keywords=Bärenmarke&r=1%3Aaps%2Ck%3Abaerenmarke. Accessed May 24, 2015.


