Original Article

Cardiovascular disease risk factors: Role of legislations that control marketing of breastmilk substitutes

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ABSTRACT

Background: Cardiovascular diseases (CVDs) are the leading cause of mortality throughout the world. Breastfeeding has been shown to play a role in the prevention of CVD. The International Code for Marketing of Breastmilk Substitutes (BMSs) and its relevant resolutions (the Code) were adopted by the World Health Assembly to protect breastfeeding. **Aim:** This study aims to study the relationships between breastfeeding rates and laws that cover the code with CVD risk factors (obesity and blood pressure) and death from non-communicable diseases (NCDs). **Methods:** Data for scores given to national laws and provisions under the Code for protecting breastfeeding were obtained from the World Health Organization (WHO)/International Baby Food Action Network report in 2020. Data for exclusive breastfeeding (EBF) during infancy were obtained from United Nations International Children's Emergency Fund Global data. The WHO data for CVD risk factors in adults (>18 years) included overweight, obesity raised blood pressure (RBP), raised blood glucose level (RBGL), and death from NCDs. **Results:** There were significant negative correlations of overweight, obesity, raised BP, and death from NCD with EBF and with scores given to national laws that cover the Code. RBGL correlated negatively with overweight and obesity. Overweight, obesity, RBP, and death from NCDs correlated inversely with provisions in the national laws for monitoring and enforcement at $p<0.015$. Engagement of health staff and systems and promotion in health facilities correlated with RBP and death from NCDs at $p<0.01$. **Conclusions:** Prevention of CVD can benefit from improving breastfeeding rates by the enactment of national laws that cover the Code in its entirety. All countries should enact, monitor, and enforce these laws for promoting and protecting breastfeeding and preventing long-term consequences of feeding BMS.

Key words: Breastmilk substitutes, Cardiovascular disease, Hypertension, Marketing, Obesity, Protecting breastfeeding, The code

Cardiovascular diseases (CVDs) are the leading cause of death, among non-communicable diseases (NCDs) globally. Risk factors for CVDs include obesity, overweight, and laboratory biomarkers as high-density lipoproteins and highly sensitive C-reactive protein [1]. Worldwide, more than 70% of all deaths are due to NCDs and an estimated 41 million people are at risk of death from heart attacks, stroke, cancer, chronic respiratory diseases, diabetes, or a mental disorder. CVDs share key modifiable behavioral risk factors such as tobacco use, unhealthy diet, lack of physical activity, and the harmful use of alcohol, which, in turn, lead to overweight and obesity, raised blood pressure (RBP), and raised cholesterol, and ultimately CVDs [2]. Majority of premature deaths (82%) occur in low- and middle-income countries and cause cumulative economic losses estimated at US$ 7 trillion [3]. A global target has been set to reduce the overall mortality from CVDs, cancer, diabetes, or chronic respiratory diseases by 25% through a Global NCD Action Plan 2013–2020 [4].

Breastmilk is a unique biological source of nutrition for infants to reach their full potential for growth and development [5,6]. Introduction of any kind of milk or food as replacement of breastmilk before 6 months of age can lead to many short- and long-term diseases [7]. Marketing milk formulas undermine a mother's decision to exclusively breastfeed (EBF) in the first 6 months of life and continue breastfeeding for 2 years, as recommended by international and scientific associations [8]. The International Code of Marketing of Breastmilk Substitutes (BMSs) was adopted by the World Health Assembly (WHA) in 1981 [9] and was followed by a series of relevant resolutions (the Code) to control the emerging marketing tactics for BMS [8]. Enforcement of the code, in its entirety, through national laws and monitoring implementation by reporting and taking corrective action for detected violations has been shown to improve breastfeeding rates [10].

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Early infant feeding practices may influence the development of CVDs. Breastfeeding is associated with preventing obesity, high blood pressure, diabetes mellitus (DM), and cancer [11]. EBF seems to have a protective effect against some risk factors for CVDs in later stage of life [12-14]. In fact, in a study, breastfeeding was associated with lowering of later blood pressure [15]. Women who breastfeed are at decreased risk of developing CVDs [16]. However, there are some controversial findings that such risk factors may be associated with the reduction of CVDs [17].

This study aims to present the status of national laws that cover the Code provisions in 89 countries and some selected risk factors for CVDs such as overweight, obesity, raised blood sugar, and RBP. It also investigates the associations between the risk factors for CVDs and breastfeeding indicators for protection and promotion.

METHODS

This is a cross-sectional observational study based on the global data from national reports from various countries, validated by international organizations, and added to the global database of the World Health Organization (WHO). The country data were obtained from the WHO NCD report in 2015 [3] and included age-standardized adjusted estimates of obesity (body mass index [BMI]>30) and overweight (BMI>25); also age-standardized adjusted estimates for raised blood glucose level (RBGL) (fasting glucose ≥ 7.0 mmol/l; 126 mg/dl) or on medication for RBGL or history of diagnosis of diabetes and RBP (systolic blood pressure≥ 140 and/or diastolic blood pressure≥ 90) [3]. The percent deaths from NCDs were obtained from the WHO NCD report for countries in 2020 [18].

The data for the status of implementation of the national laws that cover the provisions under the Code of marketing of BMS were obtained from the most recent report for status on national implementation of the Code by the WHO and International Baby Food Action Network (IBFAN) in 2020 [19]. Data for EBF were obtained from the United Nations International Children's Emergency Fund (UNICEF) database for infant feeding practices updated to 2019 [20]. EBF is defined as babies who receive only breastmilk (medicine, vitamins, and minerals included) in the first 6 months of life (0–5 months). The countries were filtered according to the availability of global data for national laws, risk factors for NCDs, and EBF data. Accordingly, 89 countries were studied and included the following based on the six WHO regions to which they are affiliated in alphabetical order included: (1) The African Region (AFR) [21]: Algeria, Benin, Botswana, Burkina Faso, Cameroon, Chad, Comoros, Côte d'Ivoire, Ethiopia, Gabon, Gambia, Ghana, Kenya, Madagascar, Malawi, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Uganda, the United Republic of Tanzania, Zambia, and Zimbabwe; (2) the American Region (AMR)[14]: Bolivia, Brazil, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Honduras, Mexico, Nicaragua, Paraguay, Peru, Trinidad and Tobago, and Uruguay; (3) the Eastern Mediterranean Region (EMR) [15]: Afghanistan, Bahrain, Egypt, Iran (Islamic Republic of), Iraq, Jordan, Kuwait, Oman, Pakistan, Saudi Arabia, Sudan, Syrian Arab Republic, Tunisia, the United

Arab Emirates, and Yemen; (4) the European Region (EUR) [22]: Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Albania, Ireland, Italy, Kazakhstan, Kyrgyzstan, Luxembourg, the Netherlands, Norway, Republic of Moldova, Serbia, Spain, Sweden, Switzerland, Tajikistan, Turkey, Turkmenistan, the United Kingdom, and Ukraine; (5) the South East Asia Region (SEAR) [7]: Bangladesh, India, Indonesia, Maldives, Myanmar, Nepal, and Thailand; and (6) the West Pacific Region (WPR) [6]: China, Lao People's Democratic Republic, Mongolia, the Philippines and Solomon Islands, and Viet Nam.

The provisions under the national laws that cover the International Code of Marketing BMS and the subsequent relevant WHA resolutions [18] are intended to protect breastfeeding. The national laws were analyzed using a checklist of relevant provisions covered under subsequent WHA resolutions, including the guidance associated with WHA 69.9. All legal national measures were scored according to how well they reflect the recommendations put forward in the Code. Each provision of the Code was given a point value, with the total points adding up to 100. Seven provisions underwent analysis in this study, including the following: (1) Monitoring and enforcement (10 points): This identifies who is responsible for monitoring compliance, defines sanctions for violations, and requires that monitoring and enforcement should be independent, transparent, and free from commercial influence; (2) promotion in health-care facilities (10 points): This type of prohibition explicitly includes display of products under scope, display of placards or posters concerning these products, distribution of any material provided by a manufacturer or distributer, use of health facility to host events, contests, or campaigns and use of personnel provided by or paid by manufacturers and distributers; and (3) engagement with health workers (HWs) and health systems (HSs) (15 points) by gifts or incentive that includes financial or material inducements to promote BMS as well as fellowships, study tours, research grants, attendance at professional conference (disclosure to the institution if fellowships not prohibited), provision of free or low-cost supplies in any part of the HS, donations of equipment or services, (or donations prohibited only if they refer to a proprietary product), product samples, product information, product information restricted to scientific and factual matters, and sponsorship of meetings for scientific and health professionals.

Data were represented as mean±standard deviation and statistics analysis was performed by ANOVA to estimate the F-ratio, *post hoc* tests to compare between individual groups using "Least significant difference" and Bonferroni tests. A comparison was made between EMR-WHO and other WHO regions. Pearson correlation was used for parametric data and Spearman correlation coefficient for non-parametric data was used to correlate the data for the national legal measures that cover the Code with the data on risk factors to NCDs and illustrated by scatter charts of Excel (Windows 10). p<0.05 was considered statistically significant. The results were analyzed and comparison was made between countries of the region for the data collected using SPSS package.

RESULTS

Table 1 compares the mean age-standardized adjusted estimates (age >18 years) for overweight, obesity, RBGL, and RBP in the 89 countries by region as per the WHO classification.

Table 2 presents the distribution of countries by the presence of legal measures that are relevant to the Code relative to the number of studies included in the study.

Table 3 compares the mean score for the score given to the national law in the 89 countries by region. *Post hoc* analysis showed that mean scores for monitoring and enforcement were significantly higher in EMR than in EUR (p<0.05) but lower than other regions (p>0.05) and EUR was significantly lower than all other regions (p<0.05).

Table 4 presents correlative studies of EBF and the total score of national laws that cover the Code with overweight, obesity, RBP, and RBGL as risk factors of CVDs and death from NCDs in the EMR versus other regions of the WHO.

DISCUSSION

Scores for laws covering the Code were highest in countries from the SEAR and EMR. The high-income countries (HICs) mostly in EUR and AMR covered fewer provisions in their legal measures in protecting the Code, particularly for monitoring and enforcement. Protecting breastfeeding through legal enforcement of the Code and monitoring implementation using the NetCode kit developed by IBFAN, UNICEF, and the WHO is important to ensure continued compliance to the Code [21,22]. The WHO status report and the IBFAN in 2020 showed that 136 countries had national laws that cover the provisions required under the Code [19].

The mean age-standardized adjusted estimates of overweight were highest in the EMR, AFR, and EUR countries. Mean regional estimates of obesity were highest in EMR countries. This may be because countries with high economies in the EMR have the highest ranks and rates of obesity in the world as Saudi Arabia,

Table 1: Comparison of the mean age-standardized adjusted estimates (age>18 years) for overweight, obesity, raised blood glucose, RBP, and death from non-communicable diseases in 89 countries by region

Region	AMR	AFR	EMR	EUR	SEAR	WPR	F	p
Overweight (BMI≥25)								
Number (Mean±SD)	25 (30.6±10.4)	14 (56.09±4.8)	15 (56.1±18.9)	22 (55.9±5.2)	7 (22.7±5.3)	6 (34.7±17.1)	25.2	0.00
Obesity (BMI≥30)								
Number (Mean±SD)	25 (8.7±5.7)	14 (19.5±3.9)	15 (22.6±10.9)	22 (19.1±3.7)	7 (4.2±1.8)	6 (9.4±3.8)	17.1	0.00
RBP (SBP≥140 and/or DBP≥90)								
Number (Mean±SD)	25 (22.6±5.0)	14 (19.9±3.4)	15 (21.1±2.7)	22 (26.9±5.1)	7 (21.7±2.1)	6 (20.6±2.9)	6.55	0.000
RBG (fasting glucose≥7.0 mmol/l (126 mg/dl) or on medication for RBG)								
Number (Mean±SD)	25 (8.9±1.9)	14 (9.5±2.3)	15 (9.5±2.3)	22 (15.1±3.3)	7 (9.2±1.04)	6 (10.0±3.8)	11.73	0.000
Death from non-communicable diseases								
Number (Mean±SD)	25 (37±10.4)	14 (74.6±6.1)	15 (67.9±14.6)	22 (88.5±5.9)	7 (70.7±7.02)	6 (73.7±10.4)	72.94	0.000

BMI: Body mass index, SD: Standard deviation, SBP: Systolic blood pressure, DBP: Diastolic blood pressure p: Probability. RBP: Raised blood pressure, RBG: Raised blood glucose

Table 2: Distribution of countries by the presence of legal measures that are relevant to the Code relative to the number of countries included in the study

Region	Countries with no legal measures		Countries with legal measures included in the study		Countries with legal measures not included in the study		Total number of countries with known status*	
	No	Percentage	No	Percentage	No	Percentage	No	Percentage
AFR	13	30.2	25	58.2	5	11.6	43	100
AMR	17	41.5	14	34.1	10	24.4	41	100
EMR**	4	19.1	15	71.4	2	9.5	21	100
EUR	3	5.7	22	41.5	28	52.8	53	100
SEAR	2	20	7	70	1	10	10	100
WPR	14	58.3	6	25	4	16.7	24	100
Total	53	27.6	89	46.4	50	26.0	192	100

AFR: African region, AMR: Americas region, EMR: Eastern Mediterranean region, EUR: European region, SEAR: South East Asia region, WPR: West Pacific region. *Source: WHO/IBFAN, 2020. **State of Palestine has legal measures but not included in the global report. IBFAN: International Baby Food Action Network

Table 3: Comparison of the mean score given to the national laws covering the Code of marketing BMS and its provisions in the 89 countries by region

Region	AMR	AFR	EMR	EUR	SEAR	WPR	F	P
EBF (0–5 months)								
Number (Mean±SD)	24 (31.5±16.0)	14 (35.9±19.9)	14 (44.7±17.7)	22 (34.1±17.1)	7 (36.6±19.8)	6 (29.8±26.4)	1.09	0.4
Total score given to national law (score=100)								
Number (Mean±SD)	25 (61.8±20.0)	14 (52.5±16.8)	15 (60.3±21.3)	22 (43.3±18.7)	7 (68.7±18.9)	6 (62.0±21.4)	3.26	0.010
Monitoring and enforcement (Score=10)								
Number (Mean±SD)	25 (6.8±2.7)	14 (6.6±3.1)	15 (5.9±3.3)	22 (2.2±3.2)	7 (8.3±0.76)	6 (9.0±1.1)	10.5	0.000
Promotion in health facilities (Score=10)								
Number (Mean±SD)	25 (8.6±3.25)	14 (7.9±4.2)	15 (8.7±3.5)	22 (3.3±4.5)	7 (8.6±3.8)	6 (8.7±3.2)	6.11	0.000
Engagement of HWs and HSs (Score=15)								
Number (Mean±SD)	25 (6.6±3.7)	14 (3.4±2.6)	15 (7.1±4.7)	22 (2.3±3.9)	7 (6.9±4.8)	6 (6.7±5.7)	4.37	0.001

AFR: African region, AMR: Americas region, EMR: Eastern Mediterranean region, EUR: European region, SEAR: South East Asia region, WPR: West Pacific region, p: Probability, BMS: Breast-milk substitutes, EBF: Exclusive breastfeeding, HW: Health workers, HS: Health system

Table 4: Correlation of EBF and national laws that cover the Code with risk factors of CVD in the 89 countries under study

Variables	Raised blood sugar ^	RBP ^	Overweight (BMI>25)	Obesity (BMI>30)	Death from NCD ^^
EBF	r-0.004	r-0.25*	r-0.3**	r0.3**	r-0.3**
National law covering code	r-0.01	r-0.24*	r-0.4**	r-0.3**	r-0.4**
Overweight	r-0.4**	r-0.01	-	r0.9**	r0.63**
Obesity	r-0.5**	r-0.01	-r0.9	-	r0.56**
Monitoring enforcement	r0.1	r-0.3**	r-0.3**	r-0.3*	r-0.3**
Promotion in health facilities	r0.2	r-0.3**	r-0.2	r-0.2	r-0.5**
Engagement of HW	r0.1	r-0.4**	r-0.2	r-0.2	r-0.5**

BMI: Body mass index, EBF: Exclusive breastfeeding, NCD: Non-communicable disease, r: Pearson correlation, *correlation is significant at the 0.05 level (two tailed), **correlation is significant at the 0.01 level (two tailed), ^ estimates in 2014, ^^ estimates in 2020. CVD: Cardiovascular disease, RBP: Raised blood pressure

Kuwait, and Egypt. A similar pattern was shown by countries in the western economies as Europe and the USA, suggesting that obesity is linked to affluence [23].

Our study showed that there were significant associations between EBF with overweight and obesity. These associations show that enactment of the Code in its entirety into the national laws can improve EBF, as well as overweight and obesity as risk factors of CVDs [24]. Moreover, violations of the Code were more prevalent in countries with high rates of overweight and obesity [8].

Mean adjusted standardized estimates of RBP were highest in the countries of EMR. RBP is an underlying cause of CVDs as well as cerebrovascular incidents increasing physical handicap, health-care costs for treatment, and resulting in premature deaths from NCDs. A longer duration of breastfeeding has been associated with a risk reduction in hypertension and myocardial infarction and T2DM [25].

Mean age-standardized estimates of RBGL is a risk factor of DM. Countries such as Kuwait and Saudi Arabia have the highest rates of DM [18]. Breastfeeding seems to exert significant protection against DM in breastfed children and their mothers; as 1–3 months of lactation reduce the cumulative incidence of DM by 80% [25].

The national legal measures for monitoring and enforcement were two-thirds of the expected score in the EMR countries but lowest in the developed countries as in European and WPRs. Breastfeeding protection through Code monitoring and enforcement is associated with the risk factors and death from CVDs [26].

Enforcement of laws is challenged by lack of clarity, knowledge and resources, the influence of cultural factors, and poverty illiteracy [27]. Civil society and media are key to monitoring the implementation of laws, but it is member states (MSs) responsibility to enact them. Civil society plays an important role in enforcing laws [28], through demanding their rights, holding their governments and duty bearers accountable, and challenge violations in criminal and civil courts. Furthermore, raising awareness of the laws and their importance in influencing breastfeeding rates and demands enforcement where there is impunity [29]. Laws regulating manufacturing, marketing, and food safety must go hand in hand with laws that address CVD risk factors including tobacco and alcohol consumption, and diet-related diseases such as laws that control the marketing of foods and beverages high in fat, sugar, or salt [30]. Laws and regulation are key tools that can support desired policy outcomes and management of inputs and processes related to breastfeeding promotion [31].

Most countries have adopted recommendations of EBF for 6 months. The European Society for Pediatric Gastroenterology, Hepatology and Nutrition Committee on Nutrition advises complementary feeding not to start before 4 months nor be delayed beyond 26 weeks (6 months), which is in contrary to the WHO recommendations of 6 months [32]. The BMS industry in Kenya is a major sponsor of HWs and systems through sponsoring their events and giving out gifts to distribute and prescribe their products to mothers. They target HWs who are the primary source of prescribing infant milk formulas. Such tactics need to be controlled by strong policies and laws.

Early introduction of supplements at birth or before 6 months interferes with the lactation reflexes and gradually diminishes the supply and effectiveness of intrinsic mechanisms for milk production [33]. They also alter intestinal microbiota and microbiomes which, in turn, predispose to the development of obesity, atherosclerosis, RBP, insulin resistance, and DM [34,35].

Death from NCD was high in the EMR but still lower than EUR, AMR, WPR, and SEAR. NCDs deaths in AFR were significantly lower than in other regions. A longer duration of breastfeeding has been associated with a risk reduction in breast cancer, ovarian cancer, endometrial cancer metabolic syndrome hypertension and myocardial infarction, and T2DM [25,36,37]. Hence, legal measures that do not cover the Code in its entirety were associated with less breastfeeding and thereby increased risk to RBP and DM mostly in HIC in EMR, EUR, and AMR.

The link between EBF and development of CVDs and NCDs may be explained by the gut microbiota. Researchers show that breastfed babies' microbiota are different than formula-fed ones [38]. There is evidence indicating that gut microbiota turbulence during the vital developmental window of early infancy leads to an increased risk of chronic non-infectious diseases in later life [39]. EBF in the first 6 months of life is important in preserving the "friendly microbiota" and thereby preventing the turbulence in the microbiota that can, in turn, modulate immune responses [40]. In effect, EBF modulate immune responses later in life and predispose to CVDs and their related risk factors [40]. Since, infant milk formula promotion can undermine breastfeeding practices, hence, regulations and laws that control marketing practices can reduce the burden of CVDs and deaths from NCDs [41].

In May 2012, the 65th WHA endorsed a Comprehensive plan on Maternal, Infant, and Young Child Nutrition that included halting the epidemic of obesity and promoting breastfeeding. Malnutrition includes overweight and obesity which are risk factors of CVDs and hypertensive disease. It begins in early infancy and can be prevented by optimal infant feeding practices [42,43]. The current study shows that breastfeeding protection, through the appropriate implementation of the Code, is associated with improved breastfeeding rates. The study also demonstrates an association between national laws that cover the Code of the prevention of CVDs risk factors.

However, a substantial number of countries do not have legal measures, which limited our ability to include more countries in our study. Regions with developed economies as the EUR have a large number of countries with legal measures but they were mostly characterized by having some provisions and thereby low scores. This interfered with our ability to relate to the degree to which these provisions influence the risk factors of NCDs. Furthermore, many countries in the EUR did not have breastfeeding indicators, hence, only 50% of the countries were included.

CONCLUSION

The current study shows that regulatory measures and early feeding practices are associated with the prevention of CVD risk factors and death from NCD. MSs and governmental implementing bodies globally should work on imposing laws and regulations that cover the Code in its entirety and are enforced and closely monitored. HWs and HSs need to be thoroughly aware and convinced to protect their clientele by implementing the Code and avoid commercial influence or conflicts of interest in their practice. Strategies that control overweight, obesity, and NCDs should include breastfeeding protection. Breastfeeding protection and promotion should be prioritized as the best nutrition source for infants and that early feeding with BMS may endanger the child and predispose to CVDs and death from NCDs. Adoption of stricter regulatory frameworks coupled with independent, quantitative monitoring and compliance enforcement is needed to counter the impacts of formula marketing on CVDs and NCDs globally. The hazards of formula feeding on both infant and mother health should be made known to the public and policy-makers [43,44]. This needs to be integrated into policies not only in HSs but also in media, educational systems, industry, and legal structures for achieving health for all.

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