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Recommendations for Adopting the International Code of Marketing of Breast-milk Substitutes into United States Policy

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Abstract

In 1981, the World Health Organization adopted the *International Code of Marketing of Breast-milk Substitutes* (International Code), with subsequent resolutions adopted since then. The International Code contributes to the safe and adequate provision of nutrition for infants by protecting and promoting breastfeeding and ensuring that breast milk substitutes, when necessary, are used properly through adequate information and appropriate marketing and distribution. Despite the World Health Organization recommendations for all member nations to implement the International Code in its entirety, the United States has yet to take action to translate it into any national measures. In 2012, only 22.3% of infants in the United States met the American Academy of Pediatrics recommendation of at least 6 months of exclusive breastfeeding. Countries adopting legislation reflecting the provisions of the International Code have seen increases in breastfeeding rates. This article discusses recommendations for translating the International Code into United States policy. Adopting legislation that implements, monitors, and enforces the International Code in its entirety has the potential to contribute to increased rates of breastfeeding in the United States, which can lead to improved health outcomes in both infants and breastfeeding mothers.

Background

In 1981, the World Health Organization (WHO) adopted the *International Code of Marketing of Breast-milk Substitutes* (International Code), with subsequent resolutions adopted. The International Code (1981) contributes to the safe and adequate provision of nutrition for infants by protecting and promoting breastfeeding and ensuring that breast milk substitutes, when necessary, are used properly through adequate information and appropriate marketing and distribution (Table 1). Member organizations are urged to implement the International Code in its entirety; translate it into national legislation, regulations or other measures; involve all concerned sectors and parties in its implementation and observance; and monitor compliance (WHO, 1981; WHO, 2016). A report by the WHO (2013) showed

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Conflict of Interests

The Authors declare that there is no conflict of interest.

that as of April 2011, 165 (83%) out of 199 countries reporting had translated the International Code (1981) into a national measure. While 64% of the 165 countries included in the report have adopted national legislation endorsing the International Code (1981), only 22% have legislation that reflects all of its recommendations. Despite 83% of countries having translated the International Code (1981) into national measures, the United States (US) has taken no action (WHO, 2013). In order to ensure that optimal levels of breastfeeding can be achieved, the US should pass legislation that adopts and enforces all aspects of the International Code (1981). The objectives of this article are to lay out the potential for success, highlight areas of current support, address potential challenges, and provide policy recommendations for the US related to the International Code (1981).

Breastfeeding is associated with a lower risk of numerous health conditions including asthma (Lodge et al., 2015), otitis media (Bowatte et al, 2015), obesity and type 2 diabetes (Horta, Mola, & Victora, 2015). In addition to benefiting infants, breastfeeding may protect mothers against numerous health conditions, including some cancers (Chowdhury et al., 2015), type 2 diabetes (Aune, Norat, Romundstad, & Vatten, 2014), hypertension and cardiovascular disease (American Academy of Pediatrics [AAP] Section on Breastfeeding, 2012). The AAP recommends exclusive breastfeeding for 6 months, followed by continued breastfeeding with the introduction of complementary foods for one year or longer as mutually desired by the infant and mother (AAP Section on Breastfeeding, 2012). In 2012, 80% of infants in the US had ever been breastfed. At six months, 51.8% of infants were breastfed, with only 22.3% being exclusively breastfed (Centers for Disease Control and Prevention [CDC], 2016b).

Policy Recommendations

Recommended legislative actions to help promote successful implementation of the International Code (1981) within the US are outlined in Table 1. Because different parts of the legislation may take more time to implement, a staged implementation is recommended. Formula companies are fully aware of the International Code (1981), with many claiming to support it, yet independent organizations continuously find them in violation (Barennes et al., 2015). The requirement to stop advertising products within the scope of the International Code (1981), including the distribution of free samples, should go into effect and require full compliance once legislation is passed. Provisions that may take longer to implement should have more time before compliance is required. A compliance date of two years after establishment of new regulations for labeling and quality requirements, for example, is recommended based on the compliance period for the nutrition and supplement facts label revision (US Food and Drug Administration, 2017).

Fines related to violations of the legislation should be imposed and strictly enforced on formula companies and the healthcare industry, with the amount increasing for subsequent violations. In 2011, Indonesia passed a strict law related to the International Code with violators facing penalties that could include fines of 100 million rupiah (approximately US $7572.90) or a prison term of 1 year (Barennes, Slesak, Goyet, & Srour, 2015). Two years after the passage of strict legislation in the Philippines banning free and subsidized infant formula from being distributed to hospitals that included fines and imprisonment for

violators, the proportion of health facilities receiving infant formula as gifts decreased by 95% (Popkin, Fernandez, & Avila, 1990). Many countries face challenges with implementation of laws related to the International Code, so a strict monitoring and enforcement system needs to be in place in order for the legislation to be most effective (Barennes et al., 2015). The US Food and Drug Administration currently oversees regulations related to infant formula and would make an ideal organization for enforcing legislation related to the International Code (1981). Additional staff should be hired to specifically monitor the new aspects of the policy. The Joint Commission, the largest healthcare accreditation body in the United States, sets standards for healthcare organizations focused on quality of care and patient safety for its accreditation and certification processes (The Joint Commission, 2017). As another level of monitoring and enforcement within the healthcare industry, relevant aspects of the International Code (1981) should also be incorporated into accreditation standards for the Joint Commission. The Joint Commission already collects data on exclusive breastfeeding during hospitalization in its perinatal core measures (The Joint Commission, 2015).

Evidence for Potential Success

Countries adopting legislation reflecting the International Code (1981) provisions have seen increases in breastfeeding rates (Barennes et al., 2015). A report by *Save the Children* indicates that national policies, including adoption and implementation of national legislation related to the International Code (1981), have been a key element in countries where breastfeeding rates have increased (McFadden, Kenney-Muir, Whitford, & Renfrew, 2015). Factors associated with success in adopting and implementing the International Code (1981) included collaborations between global and national organizations that advocated using consistent breastfeeding messages, worked across government sectors, and had an agreed upon a plan of action with roles and responsibilities specified (McFadden et al., 2015). In order to be most successful, plans should address implementing, monitoring and enforcing legislation related to the International Code (1981); focus on both community support and health facilities; achieve community support through using the media; and ensure that all health workers interacting with women, infants and families have adequate training in providing breastfeeding support that is evidence-based (McFadden et al., 2015).

Numerous agencies and national objectives for health improvement within the US government consider increasing breastfeeding rates a priority (Office of the Surgeon General, CDC, Office on Women's Health, 2011; CDC, 2013; US Department of health and Human Services, 2016). A variety of legislation and initiatives exist within the US aimed at supporting breastfeeding, including implementation of aspects of the International Code (1981). *The Baby-Friendly Hospital Initiative* (BFHI), launched in 1991 by WHO and the United Nations Children's Fund, recognizes hospitals and birthing centers who successfully implement the *Ten Steps to Successful Breastfeeding (Ten Steps)* and the International Code (1981). As of March 2, 2017, 416 hospitals and birthing centers in the US held the BFHI designation (Baby-Friendly USA, 2016). In October 2013, California passed Senate Bill 402, requiring all perinatal hospitals in California to adopt the *Ten Steps* by January 1, 2025. *Ban the Bags*, a national campaign led by the nonprofit organization Public Citizen, aims to stop formula companies from marketing in maternity hospitals. According to their data,

1,031 hospitals and birth centers have banned the distribution of formula bags as of March, 5 2017 (Ban the Bags, 2016). In 2010, federal legislation supporting breastfeeding was included in the Patient Protection Affordable Care Act, which includes provisions such requiring employers to provide reasonable break time and location for employees to express breast milk (US Department of Labor, 2010). These examples demonstrate that there would likely be support for US federal legislation related to the International Code (1981) among numerous stakeholders, and that Congress has the power to enact it.

Exposure to formula marketing has been associated with a decrease in exclusive breastfeeding. Mothers exposed to print or online infant formula information are less likely to initiate breastfeeding and more likely to intend to use formula or to intend to use formula earlier than those not exposed (Zhang, Carlton, & Fein, 2013). Receiving formula sample packs at discharge is associated with decreased exclusive breastfeeding (Rosenberg, Eastham, Kasehagen & Sandoval, 2008; Feldman, et al., 2012).

Designation as *Baby-Friendly* or adhering to the *Ten Steps*, which includes a written breastfeeding policy consistent with the International Code (1981), without designation has been associated with improved breastfeeding outcomes (Pérez-Escamilla, Martinez, & Segura-Pérez, 2016). Education and training of healthcare providers is important for success, as providers who received more training have been shown to be more likely to comply with *Baby-Friendly* practices (Pérez-Escamilla et al., 2016).

Potential Challenges

Although there is support around breastfeeding in the US, passing legislation related to adopting the International Code (1981) will likely face challenges. One of the biggest challenges will likely be the formula industry, as adhering to the International Code (1981) may cause them to lose profits. Although the industry claims to support breastfeeding, they have a conflict of interest and often put pressure on staff to increase sales (Barennes et al, 2015). Formula companies continuously commit violations of the International Code (International Baby Food Action Network, 2014). A strong monitoring and enforcement system will be critical for success.

Many healthcare systems may currently receive free or subsidized supplies. While it may be seen as a potential challenge to change procurement procedures, numerous resources in relation to the BFHI have been developed to help healthcare facilities adhere to the International Code.

Education and training for healthcare professionals on breastfeeding and the International Code (1981) is critical for success. Unfortunately, many health professional training programs do not currently include breastfeeding as a core component. The *US Breastfeeding Committee* (USBC) (2010) has developed *Core Competencies in Breastfeeding Care and Services for All Health Professionals* that can be utilized. Although many professional organizations report endorsing the competencies (USBC, 2015), a challenge to their implementation is that they are typically not included credentialing, licensing and certification of health professionals. Minimum requirements related to breastfeeding

competencies should be included in the credentialing, licensing and certification of health professionals to ensure their inclusion in training programs and continuing education opportunities.

Some may argue that enforcing the International Code (1981) may hurt mothers who cannot or choose not to breastfeed. It is important to emphasize that the International Code (1981) does not prevent the use of formula. Many provisions, such as ensuring that quality standards are in place, support infants receiving formula. Improper use of formula can be a health hazard for infants and young children, and the International Code (1981) helps ensure that information and education on their proper use is available. In framing the need to pass legislation that adopts the International Code (1981), it will be important to not just focus on the International Code (1981) in relation to breastfeeding, but instead frame it as a method to ensure that all infants, regardless of whether they are breastfed or formula-fed, receive safe and adequate nutrition.

The overall goal of adopting legislation related to the International Code (1981) is to increase breastfeeding rates. It is therefore important to evaluate the policy for its effectiveness. There are currently multiple surveys being used to assess breastfeeding rates in the US, although each has its limitations. Breastfeeding outcomes from Healthy People 2020 are currently being monitored with data from the National Immunization Survey, which has a fairly long recall period of 19–35 months post partum (CDC, 2016a). With many infants no longer being breastfeed at 19–35 months post partum, it would be useful to collect this information sooner to shorten the recall period and have more up-to-date information. Pérez-Escamilla and Chapman (2012) suggest developing a breastfeeding surveillance system that is well-coordinated and includes other related activities including the CDC state-level breastfeeding report cards and National Survey of Maternity Practices in Infant Nutrition and Care.

Conclusion

Despite the WHO recommendations for all member nations to implement the International Code (1981) in its entirety, the US has yet to take action to translate it into any national measures. Many areas of government, including the Surgeon General (2011) and CDC (2013) call for adherence to the International Code (1981) as part of a strategy to increase breastfeeding rates. Adopting legislation that implements, monitors, and enforces the International Code (1981) in its entirety has the potential to increase rates of breastfeeding in the US, which can lead to improved health outcomes in both infants and breastfeeding mothers.

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Table 1

Summary of WHO International Code Articles and Recommended Legislative Actions for the US

Article	Summary	Recommended Legislative Actions for the US
Information and education	Objective and consistent information is provided on infant and young child feeding Materials may not idealize the use of breast milk substitutes Manufacturers and distributors may only supply materials if requested and approved by the government guidelines Materials may not refer to proprietary products	Develop guidelines for educational materials on feeding infants and young children based on those outlined in the International Code Review and update educational materials related to breastfeeding provided through US government agencies such as the Office of Women's Health and the Women, Infants and Children program to ensure compliance with guidelines within one year of passage
The general public and mothers	No advertising of products within the scope of the Code No free samples of products within the scope of the Code No gifts that may promote the use of breast milk substitutes or bottle feeding No direct or indirect contact between marketing personnel and pregnant women or mothers of infants and young children	The requirement to stop advertising products within the scope of the International Code, including the distribution of free samples, should go into effect and require full compliance as soon as the legislation is passed
Healthcare systems	No promotion of products within the scope of the Code within the healthcare system No industry representatives to advise mothers No free or subsidized supplies in any part of the health care system	Allow healthcare systems a period of two years before full compliance is expected to establish new procurement procedures
Health workers	Only scientific and factual information may be provided to health professionals by companies No incentives for promoting products No free samples other than for the purpose of professional evaluation or institutional research Must disclose conflicts of interest	Require that all healthcare professionals abide by the provisions of the International Code
Persons employed by manufacturers and distributors	Company personnel may not be paid on commission for sales of products within the scope of the Code No company personnel to advise mothers and pregnant women	Require that all company personnel abide by the provisions of the International Code
Labeling	Labels should contain the words "Important Notice" or their equivalent and: • A statement of the superiority of breastfeeding • A statement that the product should only be used on the advice of a health worker as to the need for its use and the proper method of use • Instructions for appropriate preparation • Warning against the health hazards of inappropriate preparation No pictures or text idealizing the use of infant formula Food labels should state: • Ingredients • Composition/analysis of product • Storage requirements • Batch number • Expiration date No nutrition or health claims on foods for infants and young children unless allowed by national legislation	Review and update Food and Drug Administration regulations pertaining to infant formula to ensure that all labeling and quality provisions of the International Code are met Require that companies are in full compliance with new standards within two years of the establishment of the new regulations
Quality	Quality should be of high recognized standard	

Article	Summary	Recommended Legislative Actions for the US
Implementation and monitoring	Governments should implement and monitor the Code Monitoring should be carried out in a manner that is transparent, independent and free from commercial influence Member states should communicate actions taken in relation to the Code annually to the Director General of the WHO	Establish an adequately funded, strong monitoring and enforcement system Establish a comprehensive breastfeeding monitoring and surveillance system

Note: Summary content adapted from WHO (1981); WHO (2016)

[a]Products within the scope of the Code include breast milk substitutes, including infant formula; other products marketed for partial or total replacement of breast milk; and bottles and teats.