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In-Country Assessments of BMS Companies' Compliance with the International Code of Marketing of Breast-milk Substitutes

Final Indonesia Report

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Disclaimer

Westat, with its local subcontractor in Indonesia, was responsible for the collection of data related to company compliance with the International Code of Marketing of Breastmilk Substitutes and any additional country-specific regulations related to marketing of these products. Westat is responsible for the analysis of the data related to compliance with the BMS marketing standards and for preparation of summary reports that have been incorporated by ATNF into the scoring of company performance for the Access to Nutrition Index. Westat and its local subcontractor engaged with health facilities, pregnant women and mothers of infants who attended those facilities, health workers at the facilities, and retailers as part of the data collection and analysis process.

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Acronyms

ATNF	Access to Nutrition Foundation
BF	Breastfeeding
BMS	Breastmilk Substitute
DOH	Department of Health
FOF	Follow-on Formula
GUM	Growing-up Milk
IF	Infant Formula
IBFAN	International Baby Food Action Network
IGBM	Interagency Group on Breastfeeding Monitoring (IGBM)
ISMS	Institute of Social and Medical Studies
MOH	Ministry of Health
MOPH	Ministry of Public Health
UNICEF	United Nations Children's Fund
WHA	World Health Assembly
WHO	World Health Organization
IYCF	Infant and Young Child Feeding

Executive Summary

In the spring of 2015, the Access to Nutrition Foundation (ATNF) commissioned pilot population-based surveys in Jakarta, Indonesia and in Hanoi, Vietnam to systematically assess breast-milk substitute (BMS) manufacturers' compliance with the International Code of Marketing of Breast-milk Substitutes and subsequent World Health Assembly Resolutions (The Code). The purpose of these studies was to provide analysis for the Access to Nutrition Index 2016. The definition of covered BMS products is derived from both The Code and subsequent guidance issued by WHO in July 2013.[1] The Code is considered applicable to any product when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk. Products considered to be breast-milk substitutes and included in this study include infant formula (a BMS that can satisfy the normal nutritional requirements of infants up to 6 months of age); follow-on formula (for infants from the six months of age); growing-up milk (milk products generally marketed for use by infants and young children from 12-24 months); and complementary foods recommended for infants less than 6 months of age,. The Code also applies to the marketing of bottles and teats.

This report presents findings from the Indonesia pilot study. This pilot study was restricted to ten geographical areas in urban Jakarta. The results should be representative for these areas, but they should not be interpreted to apply to all of Indonesia.

The design of the survey was based, with permission from the United Nations Children's Fund (UNICEF) in New York, on a Protocol developed by the Interagency Group on Breastfeeding Monitoring (IGBM) entitled Estimating the Prevalence of Violations of The Code and National Measures. This Protocol was last updated in August 2007, and ownership of the protocol currently rests with UNICEF.[2] The IGBM Protocol calls for data collection at multiple levels to examine different aspects of Code compliance, including interviews with pregnant women and mothers of infants in health facilities, interviews with healthcare workers in health facilities, identification of informational materials produced by BMS manufacturers available in health facilities and retail stores, identification of sales promotions by BMS manufacturers in retail stores, analysis of product labels and inserts of all available products on the local market, and monitoring of media advertising. These channels of promotion were fully examined in the conduct of the survey.

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1 http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf.

2 Permission to base the survey on the IGBM protocol does not imply any endorsement of the resulting report by UNICEF.

The IGBM Protocol also requires that compliance with local measures be assessed, if they go beyond the requirements of The Code. Our BMS Code experts determined that national regulations did not expand on The Code except for inclusion of pacifiers as covered products and the addition of several items related to product labeling. These were incorporated into the data collection forms.

The methodology and procedures that were followed include the following:

- Field-level training of 14 interviewers and their supervisors was conducted in July 2015;
- Field data collection of interviews with 856 women and 127 healthcare workers in 37 health facilities was conducted in August 2015;
- Monitoring of advertising in various media was conducted during May, June and August;
- Monitoring of 111 retail outlets for observation of product promotion was performed in August; and
- Purchase and systematic analysis of the labels and inserts of 172 covered products was completed from June through August.

The major findings of the study are:

- **Sub-article 4.2. Required content of informational and educational materials dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children.** The study team identified 38 items in the 37 health facilities and 111 retail outlets that appeared to be informational or educational materials about infant feeding. Twenty-two (22) of these pertained to one or more formula products, six pertained to complementary food, two pertained to bottle, teat, or pacifier, and nine did not specify product information. They were produced by 11 BMS manufacturers. All of the 38 items had observed non-compliance, usually with most recommendations of Sub-article 4.2.

- **Sub-article 5.1. No advertising or other form of promotion to the general public of products within the scope of this Code.**[3] Overall, the media monitoring identified 495 unique advertisements from 14 of the 22 companies selling covered products in Indonesia during the monitored time period. There were 39 unique TV advertisements, aired by 6 companies, for products intended for infants up to 24 months of age, but they ran many different times. The most frequently identified sources of advertising for covered products were the Internet and Facebook.

[3] Covered products are those for children 0-24 months of age, except for complementary food, which is for 0-6 months of age.

The women most frequently recalled seeing ads for covered products on television (84.5%), in a shop or pharmacy (19.9%), and in magazines (5.6%). We are uncertain about the reliability of the women's reports on television advertising, since the media monitoring identified only 39 unique television advertisements, although these ads did run multiple times. We also observed advertisements for formula products for children of 2 years or older. It is possible that some women were recalling those advertisements.

- **Sub-article 5.2. Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.** Of the 856 women who were interviewed, 20 (2.3%) women said that they had received free samples of any BMS product from a manufacturer since the pregnancy began or the baby was born. Six (10) of the 22 companies were mentioned.

- **Sub-article 5.3. For products within the scope of this Code, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level.** Of 111 retail outlets visited, 652 promotions were identified in 94 (84.7%). The outlets where promotions were found most often were chain stores (100%) and supermarkets/hypermarkets (91.7%). Danone and Nestlé each had more than 100 promotions identified, and overall at least 10 promotions were found for the products of 9 different companies.

- **Sub-article 5.5. Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.** Of the 856 women interviewed, 25 (2.9%) reported having been spoken to by a company representative or a person at a shop or pharmacy about BMS products. All 25 women said that a particular brand or product had been recommended.

- **Sub-article 6.2. No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code.** Overall, 47 (5.5%) of the 856 women reported being spoken to by a health professional about using BMS products, and 39 (83.0%) of those professionals reportedly recommended a specific product. The most frequently mentioned companies were Nestlé (18), Danone (14) and Friesland Campina (3).

- **Sub-article 9.2, manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the points in Sub-article 9.2.** This sub-article addresses five requirements for labeling. Overall, the labeling of 98 formula and complementary food products marketed by 12 companies were analyzed. Apparent non-compliance was relatively common, with the most frequent recorded observations being (1) lack of statement that product should be used only on advice of a healthcare worker; (2) lack of instructions on appropriate preparation and health hazards of inappropriate preparation and (3) pictures that idealize use of infant formula. Of the 63 products that were coded as having pictures idealizing BMS (one product had both human and animal pictures), approximately 72%

had pictures of animals or other characters only (generally looking happy, enjoying themselves, or being cute) and 28% of these products had pictures of humans.

- **Sub-article 9.4. The label of food products within the scope of this Code should also state all of the points in Sub-article 9.4.** This sub-article addresses 5 additional requirements for labelling, and we added two items that are only mentioned at the beginning of The Code's labelling article (easy to read and appropriate language). The labeling of 98 infant formula, follow-on formula, growing-up milk, or complementary food products were analyzed. Observations were less common, with almost no non-compliance with any of these requirements.

A summary of observed non-compliance for all producers of covered formula and complementary food products found in Jakarta is presented below. This is presented for descriptive purposes only.

Executive Summary Table: Observations of Non-Compliance By Article and Source

Company	Number of formula and complementary food products in study	Total observations	Relevant sub-article			
			4.2 Facility/ store observation	5.1 Media monitoring	5.3 Store observation	9.2 and 9.4 Label analysis
Danone	27	356	12	109	210	25
Nestlé	23	357	8	173	157	19
Mead Johnson	10	127	3	78	41	5
Friesland Campina	6	101	6	30	61	4
Kalbe Morinaga	9	88	0	31	50	7
Abbott	8	46	1	20	18	7
Fonterra	3	14	0	8	3	3
Heinz	8	3	0	0	0	3
All others (4)	4	28	8	6	11	3
Total	98	1,120	38	455	551	76

Important conclusions and recommendations include:

- The most frequent type of observed non-compliance was in promotions at point-of-sale retail outlets, and this should be considered an area of major concern. Our information does not allow us to identify the extent of the role of each manufacturer in these promotions, as they could have been initiated by the retailers, companies should take all reasonable steps to ensure that distributors and retailers are aware of their responsibilities under The Code.

- We were not able to clearly interpret the women's reports of television advertising, but this is of concern, since it appears that many women may be familiar with the names of the BMS manufacturers through TV advertisements for products that are related to covered products. A review of a number of brands with products for children 0-24 months of age as well as products for older children showed that the design of packaging, colors and fonts used, was very similar across all the products in a brand.

This could cause confusion among mothers, and possible changes in packaging that might highlight the difference in products by recommended age range should be examined.

- Very notable was the substantial proportion of advertisements for covered products appearing on company and third-party websites, Facebook, Twitter, or YouTube. These sources were not a focus of the IGBM protocol, but they should receive much more attention in the future.

- The most substantial, and perhaps most controversial, aspect of labelling relates to pictures that might idealize the use of BMS. There is no definition in The Code or elsewhere for what constitutes idealization, and there is debate over whether this should apply only to pictures of humans. As our results show, the use of pictures of animals and other characters is extensive, and it is likely a marketing approach to aim to achieve compliance with The Code given the lack of clarity in this area.

- The companies that manufacture formula products were much more likely to have observed or interview-reported non-compliance with the recommendations of The Code. Those that make bottles, teats, and pacifiers do not appear to market these products extensively by providing informational materials, visiting health facilities, running advertisements, or using point-of-sale promotions.

Limitations of this pilot study include:

- Much of the information needed to assess compliance comes from interviews with women and with health care workers. Self-reported events or information can be misreported for various reasons, as described in Chapter 7.

- Health care workers were randomly selected within each health facility, but they might not have been the best workers to interview with respect to facility-related issues. The facility-level questions might best be answered by a facility manager or a financial manager.

- The selection of retail outlets to observe point-of-sale promotions was purposive, not representative. The objective was to select stores that should be most likely to have such promotions (based on probable volume of sales) so that promotions could be documented if they were occurring.

- There were no precise definitions for what should be considered non-compliance in some cases. A number of situations were noted as "gray areas", where it was not clear if something should be considered non-compliance. The most prominent example is that of what type of picture on a label should be considered as idealizing the use of a BMS.

Background 1

A. Rationale for Conducting the Pilot Study

The Access to Nutrition Foundation (ATNF) is a not-for-profit organization, based in The Netherlands, that was established in 2013 to develop and publish the Access to Nutrition Indexes (ATNIs). The first Global Index, launched in 2013, scored and rated 25 of the world's largest food and beverage manufacturers on commitments, performance and disclosure on addressing obesity and undernutrition. The ATNI is intended to (1) enable companies to benchmark their own performance against international standards and best practice and compare themselves to their peers and (2) provide an objective source of information for all stakeholders to use to evaluate companies' responses to two of the world's most pressing public health challenges.

ATNF decided to pilot, for the 2015 Global Index, an assessment in two countries of whether those companies that make breastmilk substitutes (BMS) conform fully with the provisions of the International Code of Marketing of Breast-milk Substitutes, subsequent WHA resolutions and local regulations, in order not to undermine optimal infant and young child nutrition, which are major factors in combating obesity, undernutrition, morbidity and mortality. Evidence is increasing that the initiation and duration of breastfeeding may influence obesity in later life,[4] and that breastfeeding can prevent hundreds of thousands of infant deaths and protect children throughout their lives. Breastfeeding provides strong immunity to children, reducing the risk of certain illnesses and the need for antibiotics and other medicines.[5] Indonesia was chosen as one of the countries for the pilot studies because all of the major breastmilk substitute manufacturers being assessed by ATNI sell products in the country. In Indonesia the rate of exclusive breast feeding practices for infants less than six months age was 41.5 percent in 2012.[6]

4 http://www.hsph.harvard.edu/obesity-prevention-source/obesity-causes/prenatal-postnatal-obesity/

5 http://www.who.int/features/factfiles/breastfeeding/en/

6 http://www.unicef.org/infobycountry/indonesia_statistics.html

B. The Importance of Breastfeeding for Infant and Child Health

It is estimated that 830,000 deaths could be avoided if every baby were breastfed within the first hour of life.[7] Moreover, the WHO advocates that to achieve optimal growth, development and health:

- All children should be breastfed exclusively for the first six months;
- Breastfeeding should continue until the age of two or beyond; and
- At six months old, and not before, safe and appropriate complementary foods should be introduced to infants' diets to meet their evolving nutritional requirements.

Breastfeeding confers a range of health and other benefits, as extensive evidence has demonstrated.

Babies who breastfeed are at a lower risk of:

- Gastroenteritis;
- Respiratory infections;
- Sudden infant death syndrome;
- Obesity;
- Type 1 and 2 diabetes; and
- Allergies (e.g., asthma, lactose intolerance).[8]

Several benefits to mothers have been identified, which include greater protection against breast and ovarian cancer, and hip fractures in later life. Recent evidence has demonstrated an association between prolonged breastfeeding and postmenopausal risk factors for cardiovascular (CV) disease. These illnesses all represent the greatest threats to women's health across all ages.[9] Extensive breastfeeding therefore also contributes to health service cost savings.

Nutrition and health specialists therefore encourage as many women as possible to breastfeed. In the poorest countries particularly, breastfeeding is vital to children's survival and development. While a

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7 Save the Children (2013).

8 http://www.unicef.org.uk/BabyFriendly/News-and-Research/Research/Breastfeeding-research---An-overview/

9 ibid.

small number of women cannot breastfeed, and some infants with rare metabolic diseases cannot be breastfed, the vast majority of babies can be breastfed by their mothers.

C. History and purpose of The International Code on Marketing of Breastmilk Substitutes

The World Health Organization first released the International Code for Marketing of Breastmilk Substitutes (The Code) in 1981 (see Appendix A). From 1982 through 2012, additional resolutions were adopted by the World Health Assembly (WHA) that expand on and clarify The Code, and for compliance purposes are considered part of The Code (see Appendix B).

The Code was developed as a tool to protect and promote the practice of breastfeeding and to ensure the appropriate marketing of BMS products, bottles and teats. The Code is a recommendation from the World Health Assembly calling on Governments to implement its provisions through appropriate national legislation or regulations.

D. Aspects Covered by the International Code

As interpreted for this pilot study, the definition of covered BMS products is derived from The Code, subsequent WHA resolutions, and subsequent guidance issued by WHO in July 2013.[10] According to these documents, The Code is considered to be applicable to several types of breastmilk substitutes (BMS): infant formula (for infants less than 6 months of age); follow-on formula – sometimes called follow-up formula – (for infants 6-12 months of age); growing-up milk (for children 12-24 months of age); and complementary foods recommended for infants less than 6 months of age. It is important to note that if a formula product spanned more than one age range, it was classified as belonging to the younger product type, e.g., a product listed for 0-12 months was classified as an infant formula. The Code also applies to the marketing of bottles and teats.

[10] http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf.

The Code sets out its recommendations on marketing of these products in the following articles:

- Article 1. Aim of The Code;
- Article 2. Scope of The Code;
- Article 3. Definitions;
- Article 4. Information and education;
- Article 5. The general public and mothers;
- Article 6. Health care systems;
- Article 7. Health workers;
- Article 8. Persons employed by manufacturers and distributors;
- Article 9. Labelling;
- Article 10. Quality; and
- Article 11. Implementation and monitoring.

The study focused on assessing compliance with those elements of Articles 4-9 covered by the Interagency Group on Breastfeeding Monitoring (IGBM) Protocol, which is described in Section 2B, with the specific recommendations that were to be addressed. Articles 1-3 of The Code provide the context for the pilot study but are not monitored per se. Article 10 would require special inspection of manufacturing processes, which is not covered by the IGBM Protocol and therefore not within the scope of this study. Similarly, Article 11 is primarily targeted to governmental responsibilities, is not addressed by the IGBM Protocol and was not within the scope of this study.

E. Process of Selecting Westat

ATNF initiated a competitive bid process in March 2015 by issuing a Request for Proposals (RFP) entitled "In-country assessments of BMS companies' compliance with the International Code of Marketing of BMS, and national regulation", covering assessments in two pre-selected countries, Vietnam and Indonesia. ATNF made clear that these were to be pilot studies, based on the IGBM Protocol. Westat responded to the RFP, and ATNF selected Westat in late April, at which point Westat began work on planning the in-country assessments.

F. Westat Description

Westat is an employee-owned health and social sciences research organization based in Rockville, Maryland, with more than 2,000 staff members. Westat is one of the leading survey implementation organizations in the United States, and the company has extended its expertise to the design and conduct of surveys in developing countries. Westat's professional staff includes senior statisticians with international reputations in survey sample design and statistical analysis; senior scientists in fields such as nutrition, epidemiology, and medicine; international survey experts; and global health evaluators.

Westat has not carried out studies for the infant food industry (manufacturers or business associations), nor does it have any such companies or bodies on its roster of clients. Westat has no conflict of interest in conducting and reporting on this study.

Westat has supported many national surveys for the U.S. Federal Government. Particularly relevant examples are the National Health and Nutrition Examination Survey (NHANES), the leading source of national statistics on health conditions and nutritional status of the U.S. population, which Westat has conducted for the National Center for Health Statistics for the past 20 years; and the United States Department of Agriculture (USDA) Food and Nutrition Service Infant and Toddler Feeding Practices Study, which is examining breastfeeding practices in a low income population (the Women, Infants, and Children [WIC] nutrition-assistance program).

Westat has supported health and social science research in developing countries since 1982. Westat have worked in more than 50 countries, including both Indonesia and Vietnam, and is incorporated in Thailand, which is the base for Westat's Southeast Asia activities. For these global studies, Westat has established strong management controls to ensure the quality and timeliness of work in country. Westat has also developed substantial experience in identifying qualified local partner organizations that can perform the fieldwork. See the description of Westat's local partner below.

G. In-Country Partner Description

The in-country data collection partner for this study was the Polling Center (PC), which is an Indonesian-owned and managed non-partisan agency based in Jakarta, Indonesia. PC is a leading survey research organization in Indonesia with established facilities and trained interviewing and data management staff. PC has expertise in conducting research on social, economic, and political issues. It has designed and conducted surveys for a range of partners on topics such as maternal and child health, HIV/AIDS, the environment, poverty eradication, and community development. It is experienced in quantitative and qualitative research methods and has collected data in-person, and by telephone and mail.

PC's staff includes a core team of professionals, including 13 full time experienced professionals, with expertise in research design, information technology (IT), field work, quality control, finance, and general administration. Its research and field staff adhere to standardized data collection procedures, and its data processing team follow strict data entry, cleaning, and processing procedures. PC staff have developed strong partnerships with Ministry of Health (MOH) professionals at the central, province, district and community levels, which facilitates the implementation of its research

Prior to selecting PC as an in-country data collection partner, Westat verified that PC had no commercial links to the BMS companies being assessed and that the staff of PC had no personal links to representatives of BMS companies.

H. Permission of/Support from MOH

Prior to conducting the pilot study, Westat, ATNF and the Polling Center (PC) met with the MOH to gain their support and permission to conduct the study. At the meeting, we presented our study objectives and the methodology of study and allowed the MOH the opportunity to ask any questions. Westat also assigned a local MOH liaison familiar with the rules and regulations of Indonesia to work with PC closely. PC applied for and obtained all in-country clearances required to conduct the survey. PC gained clearance to conduct the survey from the MOH Secretariat of the Health Research Ethics Committee, as is required for surveys addressing health issues.

I. Project Management

The Westat team is led by a Senior Vice President who heads international research efforts. The management team consisted of two senior managers leading work under the contract: a Project Manager and a Survey Manager, who both have substantial experience working and establishing collaborations in Southeast Asia and have existing relationships with our in-country partners. Other senior members of Westat's team included a Senior Nutrition Advisor, to advise on pilot study design and analysis; a Survey Statistician, to consult on survey sample design, weighting and variance estimates; an IT Manager and Data Manager, to ensure adequate IT support to the project and oversee database programming and data processing.

PC had a Corporate Manager to manage institutional relationships and resources, as well as a Coordinator who had primary technical responsibility for the work in-country. Westat also provided in-country consultants with strong ties to the country's MOH and expertise in infant nutrition.

Responsibilities for survey work were allocated to maximize in-country resources, while using Westat's expertise for management, development, quality control, and data analysis. Westat personnel, in collaboration with ATNF, handled the finalization of survey instruments, selection of the sample, customization of the training, programming the data entry system, cleaning and analyzing data, and preparation of the final report. PC identified the sampling frame, translated and pre-tested the survey instruments, provided training, collected and entered all data, and performed field quality control. In addition, PC assisted in questionnaire customization, interpretation of the data, and analysis through local experts in BMS, The Code, and national measures.

ATNF provided project management support to Westat by attending weekly calls for status updates and also by providing guidance at several stages of the pilot study. During the data collection process, ATNF attended bi-weekly calls with Westat and PC team supervisors.

Research Objectives 2

A. Primary Objective

The primary objective of this pilot study was to monitor compliance with the provisions of The Code, subsequent relevant WHA resolutions, and national measures, where applicable, by all BMS manufacturers selling BMS products (as defined for this study) in Jakarta. This was done by measuring the type and scale of apparent non-compliance with these provisions through interviews and observations, and attributing them to individual manufacturers. A listing of all companies that were identified as selling BMS products in Jakarta, as well as the products found by our team, is included as Appendix H. They numbered 172 products produced by 22 different manufacturers. Nearly one-half of these manufacturers produced only bottles, teats, and pacifiers. Of the 22 companies, 12 sell at least one formula product or covered complementary food. All six of the major international food and beverage manufacturers -- Abbott, Danone, Friesland Campina, Heinz, Mead Johnson, and Nestlé – marketed only formula and complementary food products, not bottles, teats, and pacifiers.

B. Pilot Study Tool

The design of the survey was based, with permission from the United Nations Children's Fund (UNICEF),[11] on a Protocol developed by the Interagency Group on Breastfeeding Monitoring (IGBM), and titled Estimating the Prevalence of Violations of The Code and National Measures. This Protocol was last updated in August 2007, and its ownership rests with UNICEF. Compliance with the provisions of The Code, subsequent relevant WHA resolutions, and national measures was measured using the IGBM Protocol (2007).[12] As noted in the preamble to this protocol, "*The Interagency Group on Breastfeeding Monitoring (IGBM) is a UK-based coalition of international non-government organisations, churches, academic institutions and interested individuals. IGBM members formed the group in 1994 in order to initiate and oversee a monitoring exercise into whether, and to what extent, the International Code of*

[11] Permission to base the survey on the IGBM protocol does not imply any endorsement of the resulting report by UNICEF.

[12] IGBM Protocol 2007 Preamble, modified.

Marketing of Breast-milk Substitutes … was being violated in selected countries. IGBM published its first report, "Cracking the Code", detailing the 1996 research findings, in 1997. … Subsequently, a review was carried out to make the IGBM Protocol more suitable for use as part of national level processes. The 2004-2007 IGBM monitoring work followed during which additional changes to the Protocol were made, and sections added, which reflect the lessons learnt during the in-country work."

ATNF selected the IGBM Protocol following recommendations from expert stakeholders they consulted. The IGBM Protocol is a tool which enables monitoring of compliance with the International Code and additionally, upon adaptation, with national regulations, in countries which have such regulations. The protocol and forms were adapted to the Indonesia context, as described in Chapter 3, Sections A and B.

The IGBM approach to monitoring compliance uses a rigorous scientific research methodology with specified sampling and a null hypothesis. The Protocol is based on sound research techniques. The Protocol is particularly appropriate for establishing a baseline indication of levels of non-compliance with The Code and/or local regulations if the latter exceed the provisions of The Code. Future research findings using this same Protocol can then be compared to the baseline, as a means of assessing the success of implementation of The Code and/or local regulations. The findings can also be used by Governments to augment their monitoring activities, and potentially to strengthen, if necessary, regulations and enforcement.

The IGBM Protocol recommends a sample size estimate of 800 interviews with pregnant women and mothers of young children to test the null hypothesis that there are no instances of non-compliance with specific Articles of The Code related to information that can be reported by the women. This sample size has 80 percent power to detect at least one reported instance of non-compliance if the true prevalence is 2 percent. For example, if 2 percent of pregnant women and mothers of infants in the total population had received a free sample of an infant formula, on average, in 80 surveys out of every 100 surveys of this size we would identify at least one instance of a woman receiving a free sample. This is a hypothesis-testing approach to sample size estimation, but in practice the survey data are used to make prevalence estimates, rather than to test hypotheses.

C. The International Code Articles Addressed in the Pilot Study

Using the sample design and the data collection forms in the IGBM Protocol, adapted to the Indonesian context and needs of this pilot study, we were able to estimate the prevalence of non-compliance for each of the following requirements of The Code.

Article 4. Information and Education

4.2 Informational and educational materials, whether written, audio, or visual, dealing with the feeding of infants, and intended to reach pregnant women and mothers of infants and young children should include clear information on all the following points:

- The benefits and superiority of breast-feeding;
- Maternal nutrition, and the preparation for and maintenance of breast-feeding;
- The negative effect on breast-feeding of introducing partial bottle-feeding;
- The difficulty of reversing the decision not to breast-feed; and
- Where needed, the proper use of infant formula, whether manufactured industrially or home-prepared.

When such materials contain information about the use of infant formula, they should include:

- The social and financial implications of its use;
- The health hazards of inappropriate foods or feeding methods; and
- Such materials should not use any pictures or text which may idealize the use of breast-milk substitutes.

4.3 Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of this Code.

Article 5. The General Public and Mothers

5.1 There should be no advertising or other form of promotion to the general public of products within the scope of this Code.

5.2 Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.

5.3 In conformity with paragraphs 1 and 2 of this Article, for products within the scope of this Code, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as

- Special displays,
- Discount coupons,
- Premiums,
- Special sales,
- Loss-leaders, and
- Tie-in sales.

5.4 Manufacturers and distributors should not distribute to pregnant women or mothers of infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding.

5.5 Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.

Article 6. Health Care Systems

6.2 No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in Article 7.2.

6.3 Facilities of health care systems should not be used for

- The display of products within the scope of this Code,
- For placards or posters concerning such products, or
- For the distribution of material provided by a manufacturer or distributor other than that, and
- Specific to Article 4.3.

6.8 Equipment and materials, in addition to those referred to in Article 4.3, donated to a health care system may bear a company's name or logo, but should not refer to any proprietary product within the scope of this Code.

Article 7. Health Workers

7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle feeding is equivalent or superior to breast-feeding. It should also include the information specified in Article 4.2.

7.3 No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.

7.4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level.

Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.

Article 9. Labelling

9.2 Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the following points:

- The words "Important Notice" or their equivalent;
- A statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;
- Instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation;
- Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product as a breastmilk substitute and for illustrating methods of preparation;
- The terms "humanized", "materialized" or similar terms should not be used;
- Inserts giving additional information about the product and its proper use, subject to the above conditions, may be included in the package or retail unit. See "type of material" code; and
- When labels give instructions for modifying a product into infant formula, the above should apply.

9.3 Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant.

9.4 The label of food products within the scope of this Code should also state all the following points:

- The ingredients used;
- The composition/analysis of the product;
- The storage conditions required;
- The batch number; and
- The date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.

Specifications for what was considered possible non-compliance with the specific recommendations, based on the data that were collected on the study's data collection forms, can be found in Appendix E.

Methodology: IGBM Protocol 3

Westat followed very closely the IGBM Protocol to conduct the study, adapted in a few minor ways where necessary, which the IGBM Protocol recommends should be done in line with specific country contexts.

A. Comparison of the International Code to the Local Regulations

Westat obtained and translated the following Indonesia national regulations: Number 15 (2014), Number 33 (2012), Number 39 ((2013), and Number 49 (2014) that are related to breastmilk substitutes. Our BMS Code experts carefully compared the national regulations with the International Code to identify products and standards that are different from The Code. The experts determined that these regulations did not expand on The Code except for inclusion of pacifiers as covered products and the addition of several items related to product labeling. For formula products, the local regulations required wording that "Infant Formula Milk is not a Sterile Product; therefore, read the Preparation Instructions" must be on the main part of the label with font size at least 2mm. For formula products and complementary foods, the local regulations required that (1) all ingredients used are listed in order from the highest to lowest amount, either horizontally or vertically; and (2) that net weight or net content be included. These regulations only cover products up to 12 months of age, with the exception of Number 49, which is to take place in 2017 and has a special provision related to growing-up milk.

B. Adaptations of Forms

As Indonesian regulations embed all key provisions of The Code, few substantive changes were needed to the forms. Local regulation includes marketing of pacifiers (as well as teats and bottles), which were therefore added as a product to be assessed through all the forms, and the extra labeling requirements were added to Form 5.

With the evolving technological age, another substantive change made was the addition of the internet and social media to Form 1 as platforms for promotion that may be recalled by pregnant women and mothers.

The forms were also amended to enable data on all types of BMS noted in Chapter 2 above to be collected and differentiated, for all companies selling products in Jakarta. Some re-formatting was done to ease data collection, which resulted in a slightly different look than those forms that exist in the Protocol. None of the customizations altered the collection of objective measures as designed in the Protocol.

All forms were translated to Indonesian Bahasa by staff of PC. The translations underwent cognitive testing by bilingual study staff in Jakarta for changes that were needed to retain the English meaning. The form translations did not alter the collection of objective measures as designed in the Protocol.

The English version of the final forms used for data collection can be found in Appendix G.

C. Data Collected

To capture information in assessing possible non-compliance with these Articles of The Code, it was necessary to:

- Interview mothers and pregnant women;
- Interview health workers;
- Evaluate promotional and educational materials found in those health care facilities visited for interviews;
- Evaluate any marketing and promotions within selected retail stores;
- Evaluate product labels and inserts of available products; and
- Monitor selected media.

The Protocol contains six data collection forms, each designed to objectively capture information from each of the unique sources and relating to specific Articles of The Code.

Form 1. Designed to collect information from pregnant women or mothers to determine whether they:

- Recalled having been advised to use infant formula or any other drink or food for infants under 6 months of age;
- Recalled receiving any sample of a breastmilk substitute, bottle, teat, or pacifier during their pregnancy or since the birth of their youngest child;
- Recalled receiving any gift of articles or utensils which may promote the use of breastmilk substitutes or bottle feeding; and
- Recalled having seen advertisements for formula milk (0-24 months of age), drinks/foods for infants under 6 months of age, bottles, teats, or pacifiers.

Form 2. Designed to collect information from health workers to assess incidents of:

- Health facilities where staff reported receiving samples of breastmilk substitutes, bottles, teats, or pacifiers in the last six months;
- Health facilities which had received free or low cost supplies of breastmilk substitutes, bottles, teats, or pacifiers in the last six months;
- Health facilities where staff reported having received at least one visit from company personnel in the last six months;
- Health facilities where staff reported having received at least one gift from company personnel in the last six months;
- Health facilities where staff reported having received, from companies in the last six months, materials or equipment; and
- Health professionals who reported having received gifts, financial or material inducements from companies in the last six months.

Form 3. Designed to collect data on information materials in selected health facilities and selected retail outlets to assess incidences of:

- Company-sponsored written information for mothers and pregnant women about infant feeding;
- Company-sponsored visual information about infant feeding or displays; and
- Company-sponsored information about infant feeding for health professionals.

Form 4. Designed to collect information on point-of-sale promotions in selected retail outlets to assess number of those retail outlets where such promotions may be.

Form 5. Designed to collect information on product labels and inserts.

Form 6. Designed to collect information on advertisements to assess the number of advertisements in the public domain.

All information collected from women focused on the period since the beginning of the pregnancy or in the 6 months since the birth of the child. Information from the health workers related to the period of six months prior to the date of the survey. All information collected from shops and other public domain areas relates to the period of the survey, reflecting the products and information as available during the time of the survey.

Clinics and health facilities were not given compensation for allowing the study to be conducted in their facility. For the participation in a pilot study interview, pregnant women or mothers were given a thank you gift as appreciation for their time (worth approximately US$ 1.90) and health workers were also given a thank you gift (worth approximately US$ 6.50), as is usual practice in Indonesia.

D. Sampling Health Care Facilities in Jakarta

Ten geographical areas (sub districts), referred to as clusters or primary sampling units (PSUs), were selected for the Indonesia assessments of compliance with the International Code of Marketing of Breastmilk Substitutes (BMS) and national regulations (see project sampling memo ATNF IS3.1 dated May 29, 2015). From the PSU frame, 167 health facilities were estimated to be located in the 10 selected clusters. The second stage sampling strategy was to select a total of 40 facilities for the in-person interviews of eligible women.

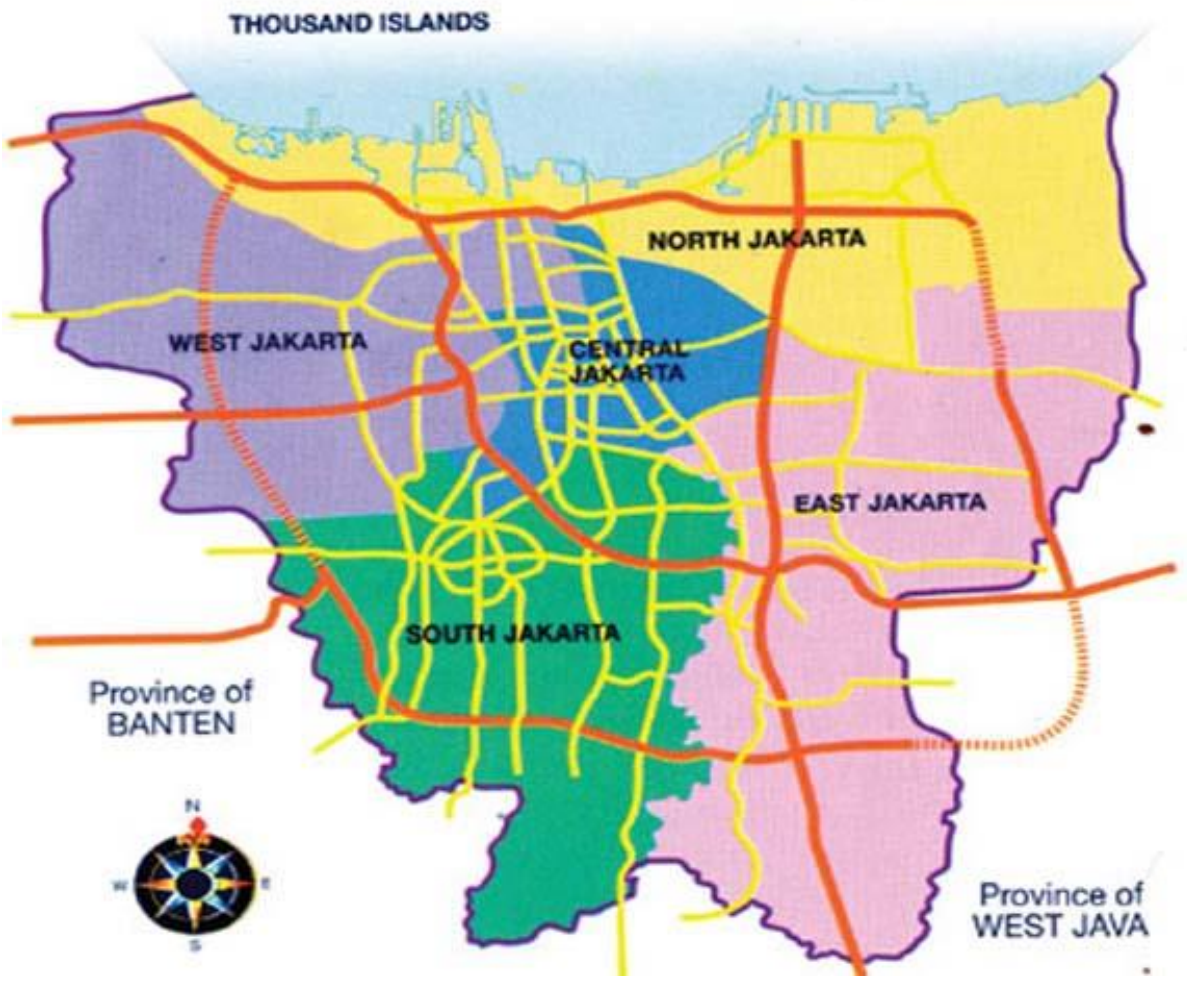
The goal was to select 40 facilities for the Indonesia assessment, 4 in each of the selected PSUs. The construction of the frame in the 10 selected PSUs resulted in 175 eligible health facilities (see Appendix A). The final number of 175 eligible facilities was therefore higher than initially estimated at the time of the selection of the PSUs. Facilities were eligible if they served at least 10 pregnant women and mothers of young infants aged 6 months or less per day on average and

operate at least 2 days a week.[13] The 40 facilities were selected using with probabilities proportionate to size (PPS) where the sub districts were essentially treated as strata and the measure of size (MOS) was the number of pregnant women and mothers of young infants aged 6 months or less served per day on average. For several facilities the number of pregnant women and mothers of young infants aged 6 months or less served per day on average was provided in a range, for example 30-50. For these facilities the MOS was set to be the midpoint of the interval.

Three facilities located in two PSUs had a large MOS and were selected with certainty, i.e., with probability of selection equal to 1. The remaining non-certainty facilities were selected systematically after ordering the frame by sub district, Kelurahan (sub division of sub district), and type of facility. The final number of facilities included in the study was 37.

Once the sample of health facilities was provided, PC began contacting the facilities and clinics to gain approval to visit and conduct interviews. An approval package had to be submitted, including a letter of support from MOH, in order to gain access to the ten large hospitals

[13] Daily rates were obtained from the Ministry of Health when possible; in some instances it was necessary to contact the facility directly to obtain an estimate.


THOUSAND ISLANDS
NORTH JAKARTA
WEST JAKARTA
CENTRAL JAKARTA
EAST JAKARTA
SOUTH JAKARTA
Province of BANTEN
Province of WEST JAVA
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E. Sampling of Women in Health Care Facilities

Study procedures called for interviews with women to be conducted over a period of two days, whenever possible. If a sufficient number of interviews could not be completed in the first two days, then the facility was visited for additional days.

For the facilities, the target was to conduct, on average, 20 interviews with women. Since it was assumed some women might not be available for the interview or might refuse to be interviewed, we attempted to select a sample of 24 women, to get an average of 20 completed interviews per facility. The selection was performed using a systematic random sampling method.

For any facility that was expected to see more than 24 eligible women over a two day period, selection of women was done as follows:

1. If a registration roster of pregnant women and mothers with children less than 6 months at the day of data collection was available, it was numbered consecutively in order of appointment time. If such a roster was not available, then an estimate was obtained of the number of eligible women the facility expected to see over the two-day period.

2. A systematic random sampling method was used to select 24 pregnant women and women with children 0-6 months from the list of women for two days of data collection, as follows:

   – The total number of women expected was divided by 24 to get the sampling interval number. For example, if the total number of women on the list was 50, the sampling interval = 50/24 = 2.1. Any fractional sampling interval was rounded up to the next whole number.

   – A random number for each facility was selected (to serve as the starting point for systematic sampling.

   – The first woman selected for interviewing was the woman with the code that matched the random digit of that facility; for example, if the random digit was 3, the third woman on the appointment list (or the third eligible woman who showed up in a facility with no appointment list) was selected. The second woman was the woman that had the code that equaled the code of first woman plus the sampling interval number.

If the end of the list was reached before 24 women were selected, the data collector circled back to the top of the list and continued to apply the sampling interval, skipping over women who have already been selected. In facilities that did not have more than 24 eligible women expect to attend over a 2-day period, all eligible women were approached without any sampling.

No replacements were made if the team failed to obtain 20 interviews. A desired minimum number of women interviewed at each facility was set at 18. After two days of data collection, if the number of women who completed interviews was less than 18, additional field-work was arranged to achieve the desired sample size, following the above sampling methodology.

A total of 856 women were interviewed. The range per facility was 18-24 interviews.

F. Sampling of Health Workers in Health Care Facilities

On arrival at the health facility, the team asked for a list of the names and designations of all health workers who have contact with pregnant women and mothers of young infants and who would be present during the days when the team would visit. For the pilot study in Jakarta, the types of health workers included, nurses, doctors, midwives, pharmacists, nursing staff, breastfeeding counselors and facility managers.

Using the list of staff names, a "fishbowl" technique was applied to randomly select the health workers for interviews. Each health worker on the list was assigned a number, which was written on separate pieces of paper, folded, and placed in a cup. Four pieces of paper were selected from the cup. The numbers were matched with the health worker names and each selected health worker was asked to be interviewed.

The IGBM Protocol called for completing only three health worker interviews per facility, but four health workers were selected to allow for any refusals to participate. If all four health workers agreed to participate, then all four were interviewed. In facilities that had four or fewer health workers available, all were selected for interview.

A total of 127 healthcare professionals were interviewed.

G. Selecting and Visiting Retailers

As part of the model for assessing compliance with The Code, it was necessary to visit a number of retailers to determine whether there were any promotions or materials for products covered by The Code. The IGBM Protocol did not specify the types or numbers of retail outlets to visit, except to say that this should be done near the health facilities that had been selected for study. We made the selection approach more specific in order to ensure consistency across the study and to target the types of retailers we believed would be most likely to offer promotions, as explained below.

The goal was to sample three retailers in close proximity to each participating health facility. There are many types of retailers in Jakarta that might sell BMS products, but our pre-test results showed that some types of retailers are unlikely to sell such products in volume. We determined that pharmacies do not sell BMS products, and that very small grocery stores sell very few BMS products. Therefore, retailer eligibility was limited primarily to those types of stores likely to sell a substantial amount of BMS products - BMS specialty stores, supermarkets, and large chain stores – unless three could not be found.

We attempted to select a store from each of these three categories around each of the participating health facilities. The plan was to identify, if possible, the store in each category that is closest to the health facility. Since there were no maps of all the stores, a healthcare worker at the facility was asked for the location of the closest store of each category. If the healthcare worker could not provide this information, we asked if any other administrative member of the staff might have information about this. If these were not successful, then an attempt to identify relevant stores was done using an Internet map search by store type near the facility location. Our searches looked for stores within a one kilometer radius of the health facility.

A total of 111 stores were visited.

H. Identifying and Evaluating BMS Products

PC assembled a list of all of the known products sold in Jakarta that are BMS according to the WHO definition and therefore subject to the International Code or the Indonesia national regulations. Products included those of major international manufacturers, other manufacturers from outside of Indonesia, and in-country manufacturers. Every product was purchased or photographed for analysis of the labels and inserts.

These products did not need to be purchased at a location near one of the sampled health facilities, since we expected the labels and inserts for products to be the same no matter where in the city they were sold. However, we did distribute the purchasing over multiple stores, and generally bought products at any retailer that was visited, since this helped the observation for promotions go more smoothly. It was not mandatory that the field teams purchase something from every store that was visited.

For purchasing, the intent was to buy the smallest size available in an effort to contain cost. We expected the labels and inserts to be the same on all sizes. However, if at the time of purchase, the Coordinator or her designee reviewed the labels on larger sizes, and if it appeared that there were substantive differences in content, the larger size was purchased instead.

If the field teams found the product list was incomplete and identified any additional products during their visits to retailers, those products were added to the overall list and a sample was purchased as well. The final list contained 172 products manufactured by 22 companies. (See Appendix H).

I. Media Monitoring

Television is the dominant medium in Indonesia, and television advertisements make up more than 64 percent of media spending in Indonesia. Newspapers are a distant second, representing about 20 percent of spending in Indonesia While spending on magazines and internet advertising is much smaller, websites dedicated to pregnant women and mothers are prolific; and based on the experience of our partners, such as the Helen Keller International's Assessment and Research on Child Feeding (ARCH) Project, these media appear to be prime locations for BMS advertisements. Therefore, we chose to monitor television and newspaper media, which receive the highest

advertising spending, as well as pregnancy and motherhood magazines and websites, plus BMS company websites, and social media websites. The Protocol does not differentiate between websites and social media in terms of internet source; however, due to the growth of social media since the development of The Protocol, Westat decided the three main social media platforms (Facebook, YouTube and Twitter) should be monitored in addition to the top websites geared towards pregnant women and mothers. However, no information is available about the percentage of advertising spent on these media.

PC entered into an agreement with the local office of an international media monitoring organization, Nielsen, that tracks television, print newspapers, and mother and baby-related magazines advertising in Indonesia. Most of the information from these sources was received in an automated fashion; therefore we monitored these media for three months, May, June and August 2015, although only one month was recommended in the Protocol. For the sources that needed to be monitored manually (e.g., BMS company local websites and social media sites), PC monitored activity for one month, August 2015.

Prior to conducting the media monitoring, Westat trained PC media monitoring staff on the protocol's Form 6 and clarified the information needed from the social media platforms and websites to ensure that everyone understood the BMS products and age ranges that should be included in the study. The following guidelines were followed by PC for specialty magazines and internet websites:

- **Specialty online Magazines and Tabloids.** The monitor visited the websites once a week and scanned for BMS advertisements. They used Microsoft Snipping Tool to capture screen shots of the advertisements.
- **Internet.** Once a week over the one-month period the monitor accessed websites related to mothers and babies, and scanned for BMS advertisements. They used Microsoft Snipping Tool to capture screen shots of the advertisements.
- **Social Media.** PC identified the most popular social media in Indonesia, which are Facebook, YouTube and Twitter. For Facebook, PC used two methods to identify the most popular Facebook pages. Socialbakers[14] was used to target baby food companies in Indonesia, and then we targeted the brands and products related to our study which included formula milk products for children 0-24 months old and baby food for those less than 6 months. From the Socialbakers website, PC identified the 10 most popular

[14] Socialbakers Analytics tracks and analyzes data from Facebook, including number of posts, number of responses and the amount of engagement with users, to provide statistics on the top brands within a certain tag.

websites that the team then monitored.[15] PC also searched for the companies' and brands' Facebook pages if they were not listed under Socialbakers. Westat discussed with the monitors what Westat considered violations and promotions on the Facebook pages to make sure everyone understood the methods prior to starting the study. For YouTube and Twitter, PC identified the advertisements by searching for brands and products.

After clarifying and identifying the Facebook, Twitter, and YouTube pages, PC assigned its media monitors to visit those pages at least once a week over the one-month period. The monitors accessed Facebook and YouTube and read through the pages for BMS advertisements or promotions related to the products and brands in the targeted age group. Once they found the advertisement or promotion, they captured the image and content on the page by using Microsoft Snipping Tool to capture screen shots, then pasted the image and content captured into Word files. They recorded the date and time the webpage was visited for reference and used Form 6 to fill out the data. The advertising count was of unique ads; if an ad was seen in more than one visit to a website, it was counted only the first time.

Data that were provided electronically by the media monitoring company were imported into the study database without use of any hard-copy form completion. The data for each advertisement were reviewed for completeness and quality, and for any items from Form 6 that were missing or inconsistent, the media monitor reviewed the video or picture of the advertisement to obtain the missing information and enter it into the database.

In total, Nielsen and PC monitored 24 TV channels, 92 printed magazines, tabloids and newspapers and 400 websites, including the local websites of the major international BMS manufacturers and 3 social media platforms (YouTube, Facebook, and Twitter) geared to pregnant women and mothers.

Data that were provided electronically by the media monitoring company were imported into the study database without use of any hard-copy form completion. The data for each advertisement were reviewed for completeness and quality, and for any items from Form 6 that were missing or inconsistent, the media monitor reviewed the video or picture of the advertisement to obtain the missing information and enter it into the database.

[15] Statistics for the top Brand pages from Facebook Vietnam in 2015 for tag "baby-food": http://www.socialbakers.com/statistics/facebook/pages/local/vietnam/brands/fmcg-food/baby-food/

J. Representativeness and Precision of Results

The design of the IGBM protocol yields a representative sample of health facilities, pregnant woman and mother of infants < 6 months old, and healthcare workers within those institutions for the sampled areas of Jakarta. Thus, the prevalence estimates for possible Code non-compliance that are reported in Chapter 5 can be considered reasonable approximations of the true prevalence within these areas for items reported by these sources. Weighting of the data from the women's interviews could change the estimates slightly, and the precision of the estimates would need to take into account the overall design effect related to clustering of facilities and women in the sample selection. The 95 percent confidence interval for any prevalence estimate based on the women's responses is approximately $\pm$ 1.5 to $\pm$ 3.0 percent. Smaller estimates have a smaller confidence interval; larger estimates have a larger confidence interval. For example, with for a prevalence estimate of 5.0 percent, the 95 percent confidence interval is approximately 3.3-6.7 percent; for a prevalence estimate of 10.0 percent, the confidence interval would be about 7.7-12.3 percent. These guidelines may be applied to any estimates in Chapter 5 that are based on women's interviews.

While the selection of health facilities and health workers is also representative of the sampled area, we do not have precise enough measures of the eligible population to make reliable confidence interval estimates. Therefore, we have not attempted to do so.

The prevalence estimates for promotions in retail outlets cannot be extrapolated to the overall catchment area of the pilot study, since the selection was a convenience sample. For product labels and media advertising, this pilot study conducted a census; therefore, the prevalence estimates do apply to the sampled area of Jakarta.

K. Defining Potential Non-Compliance

For each Article of The Code for which the IGBM Protocol collected data, our study team collated definitions from the IGBM Protocol, WHO and other authoritative sources (such as Helen Keller International and ARCH) of what would be considered non-compliance with The Code. These definitions are provided in Appendix K, organized by Sub-article of The Code, and showing the exact questions and codes that factored into defining possible non-compliance. There were some gray areas related to some recommendations, such as what constitutes a picture idealizing BMS or what type of gift is sufficient to encourage a health worker to promote a BMS product. Where we are uncertain, we have noted what data we have and how we have interpreted it.

It should be noted that for the interview data from the women and the health workers, we have emphasized that this is based on recall, and thus we are not able to verify that the reported event accurately demonstrates non-compliance with The Code. A further discussion of this limitation is presented in Chapter 7, Limitations. For items that were directly observed by our field team, such as informational materials, promotions, and product labels, we did see the actual items, and therefore we have called these "observations."

Fieldwork Preparation and Training 4

A. Organization of Polling Center Field Work

Personnel for data collection in the field included 14 data collectors, six field supervisors, one national coordinator and one assistant coordinator. Data collectors were formed into two-person teams, allowing for six teams to be in the field collecting data, each accompanied by a field supervisor.

PC also had a team of six individuals who performed data collection at the retail outlets and performed the label analysis, four individuals responsible for submitting proposals to health facilities and making appointments for the data collection staff, and four individuals conducting media monitoring of online and social media.

B. Selection and Training of Data Collectors

PC recruited a team of data collectors that were a combination of fresh graduates and those we had at least one year of experience as an interviewer. The requirement for experienced data collectors was based on previous experience. For newly graduated data collectors, the recruitment was done by spreading information to potential universities and colleges, research firm communities and social media websites. Each of the data collectors were screened and interviewed by the Project Coordinator. A total of 14 data collectors were selected.

Westat and PC held training in Jakarta for six days in late July 2015 to provide all selected data collection staff with the knowledge and skills necessary for data collection using the IGBM Protocol. The training followed the approach recommended in the Protocol, and was based on materials provided by the Protocol. It introduced the data collectors to the importance of breastfeeding, oriented them to International Code and local regulations, and trained them on the use of the IGBM questionnaires. Data collectors were provided with a PowerPoint presentation containing an overview of all information. In-depth training on using the data collection forms was provided; the data collectors practiced mock interviews and role plays to simulate use of the forms for interviewing. A field test conducted with the data collectors to give experience of visiting and

performing interviews in the clinics and ensure data collectors understood the proper interviewing techniques. Another field test was conducted for the retail outlet training to determine the stores to visit and to give experience looking for BMS products and promotions. A separate training was given to the data collectors evaluating the label and inserts of the BMS products purchased. The team also practiced how to fill out Form 4 for retail store promotions. A separate training was given to the data collectors evaluating the label and inserts of the BMS products purchased for completion of Form 5.

For further detail on the training, please find the training agenda in Appendix J.

C. Introductions to Clinics

In order to conduct the survey at the health facilities in Jakarta, we also needed to get approval from the provincial health office in Jakarta, PC submitted the approval package to the Provincial Health Office (PHO) and obtained approval to conduct the pilot study. At the public and private hospitals, we also needed to get approval from each institution's IRB. PC submitted these application packages.

The MOH and PHO provided letters to all health facilities to introduce the study being conducted by PC, and to explain that the objective of the study was to investigate the knowledge of mothers on breastfeeding and nutrition of children. The letter was used as a request from PHO for each health facility to collaborate with PC by participating in the study. The contact by PC with each facility was made as close to the planned interview date as was possible in order to allow little time for any facility to change practices because of the pilot study.

D. Data Collection and Entry

Data collectors in the field completed hard copies of the data collection forms, following the procedures outlined in the data collection training and the Protocol. The project coordinator reviewed the completed survey questionnaires for data quality, as outlined in the Protocol, by ensuring all questions were complete, legible, valid, logical, and consistent. The reviewed data collection forms were then entered into Epi Info by the data entry staff using double data entry, initialing and dating the forms after entry completion. The Westat Data Manager ran a SAS query to

reconcile all first and second pass data and provided any discrepancies to the in-country project coordinator for resolution. After data entry, all forms were placed for storage in a secure file cabinet.

Special quality control procedures were implemented for analysis of product labels. Four evaluators were trained for this task, along with two supervisors (the study coordinator and the coordinator assistant). All packages of the products were labeled with a number and all the blank forms were also pre-marked with the same product numbers. The evaluation process was carried out together in a single room, so the evaluators could consult with each other. After the evaluator filled out the form, a double check was done by the Coordinator and coordinator assistant on the first 30 percent of forms for each evaluator. If incorrect information was found among the first 30 percent for an evaluator, then the coordinator increased the amount of checked forms of that evaluator, until the evaluator's work displayed no errors.

The cleaned raw data from the field was further reviewed for completeness and accuracy by Westat's data analysts before the analysis tables were produced. Product names were reviewed and compared to known product lists found on manufacturer websites, association of each product with a specific company was verified for all formula products and complementary foods, product type was confirmed and corrected if necessary, and unclear data was returned to the field for further clarification or correction. The major manufacturers who will be evaluated by ATNF in the 2015 Access to Nutrition Index were not informed of the survey in advance. However, after the data collection was completed, they were offered the opportunity to fact-check the list of products and advertisements that we associated with their companies before the pilot study report was finalized. Any agreed inaccuracies were corrected in this final report. The number of inaccuracies that were corrected was less than five.

Pilot Study Results 5

The aim of the IGBM protocol is to assess compliance with selected Articles of the International Code and local regulations by BMS manufacturers. In practice, this is done by measuring possible non-compliance, i.e., by observing where a particular provision of The Code does not appear to be followed. The results from the analysis of data collected in the Indonesia study are presented below, organized by Article of the International Code for which data were captured in the IGBM protocol's data collection forms. For each Article, if there were a substantial number of observations, the accompanying table shows data overall and for the companies most frequently mentioned or observed with possible non-compliance.

Table 1 and Table 2 show the distribution and characteristics of the sample from which the data were collected.

Table 1. Summary of data collection by health facility

District #	Area #	Facility #	# of women interviewed	# of health workers interviewed	# of retailers visited
1	1	01	24	4	3
1	1	02	24	4	3
1	1	03	24	4	3
1	1	04	24	4	3
1	2	05	23	2	3
1	2	06	24	3	3
1	2	07	21	3	3
1	2	08	24	3	3
2	1	09	24	4	3
2	1	10	20	3	3
2	1	11	20	3	3
2	1	12	22	1	3
2	2	13	23	4	3
2	2	14	24	4	3
2	2	15	24	4	3
2	2	16	24	1	3
3	1	17	24	4	3
3	1	18	24	4	3
3	1	19	24	3	3
3	1	20	24	4	3
3	2	21	24	4	3
3	2	22	24	4	3
3	2	24	18	3	3
3	3	26	24	4	3
3	3	27	24	3	3
3	3	28	24	4	3
4	1	29	22	3	3
4	1	30	24	3	3
4	1	31	24	3	3
4	1	32	21	3	3
4	2	33	24	3	3
4	2	35	23	4	3
4	2	36	24	4	3
5	1	37	24	4	3
5	1	38	20	4	3
5	1	39	23	4	3
5	1	40	24	4	3
Subtotal		37	856	127	111
# refused		10	28	5	NA
Total		47	884	132	NA
Participation Rate		78.7%	96.8%	96.2%	NA

Table 2. Characteristics of participants

	Number	Percent
Type of Health Facility		
Hospitals	7	18.9%
Clinic	1	2.7%
Health Center	24	64.9%
Bidan (midwife center)	1	2.7%
Midwife in private practice	4	10.8%
Total facilities	37	100%
Women's Status		
Pregnant	429	50.1%
Mother of Infant < 6 months	427	49.9%
Total women interviewed	856	100%
Type of Healthcare Worker		
Doctor	31	24.4%
Nurse	37	29.1%
Midwife	56	44.1%
Breastfeeding Counselor	3	2.4%
Total workers interviewed	127	100%
Type of Retail Outlet Visited		
Breastmilk Substitute Specialty Store	26	23.4%
Chain Store	57	51.4%
Supermarket or Hypermarket	24	21.6%
Other	4	3.6%
Total retail outlets visited	111	100%

A. Article 4: Information and Education

Data were collected to allow assessment of compliance with Sub-article 4.2, informational and educational materials; and Sub-article 4.3, donations of equipment or materials to health facilities.

Sub-article 4.2. Informational and educational materials dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children

The study team identified 38 items that appeared to be informational or educational materials about infant feeding that were produced by BMS manufacturers. Twenty-four (24) of these were found in 12 different health facilities; the other 14 were found in 13 different retail outlets. Twenty-two (22) of these pertained to one or more formula products, six pertained to complementary food, two pertained to bottle, teat, or pacifier, and nine did not specify product information. In Table 3, we

present the data by product type. The total number of product types is greater than 38, since two items referred to multiple product types.

Table 3. Observations related to article 4.2: Informational and educational materials

		Infant formula	Follow On formula	Growing up milk only	Complementary food*	Bottles, teats, pacifiers	No product specified	Total
Total number of items reviewed (38 individual items, 1 covered 4 types and 1 covered 3 types)		2	3	19	6	4	9	43
Number with observations	#	2	3	19	6	4	9	43
	%	100%	100%	100%	100%	100%	100%	100%
Type of observation of non-compliance with Code								
4-1: Benefits and superiority of breastfeeding	#	1	1	18	6	0	6	32
4-2: Maternal nutrition, maintenance of breastfeeding	#	1	1	16	5	3	8	34
4-3: Negative effect of partial bottle-feeding	#	2	3	19	6	1	9	40
4-4: Difficulty reversing not breastfeeding	#	2	3	19	6	3	9	42
4-5: Proper use of infant formula	#	2	3	19	NA	NA	7	31
4-6: Letter height no less than 2 mm	#	0	0	2	0	0	3	5
4-7: Social and financial implications of using formula	#	2	3	17	NA	NA	7	29
4-8: Hazards of inappropriate foods or methods	#	2	3	18	4	4	7	38
4-9: No pictures or text idealizing BMS (human and non-human)	#	1	2	10	3	0	8	24
Company								
Danone		0	1	8	0	0	3	12
Nestlé		0	0	1	3	0	4	8
Friesland Campina		0	0	6	0	0	0	6
Mead Johnson		0	0	1	0	0	2	3
Indofood		1	1	1	1	0	0	4
Others		1	1	2	2	4	0	10

None of the 38 unique items complied with the provisions of Sub-article 4.2, with at least five incidences of non-compliance with every requirement. The provision that was complied with most frequently was having easily readable letter height, which is specific to Indonesia regulations. All of the global BMS manufacturers except Heinz had items identified. Materials were found in 12 of the 37 health facilities (32.4%) and in 13 of the 111 (11.7%) retail outlets. However, in 8 of these health facilities, only one item was found. Two health facilities had three items, and two other had five items. Although the items that we found did not comply with The Code, the use of this approach to reaching women appears to be limited now that more sophisticated, efficient and effective electronic means of communication are available.

Sub-article 4.3. Equipment or materials donated to health facilities may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of this Code

Data for this assessment were captured in interviews with healthcare workers. A total of 127 healthcare workers from 37 different facilities were interviewed. Only two workers from separate facilities reported donations; one was of leaflets and the other was of posters/calendars. Interviewers followed standard neutral interviewing techniques, and it is possible that healthcare workers would not report instances of donations.

B. Article 5: The General Public and Mothers

Data were collected to allow assessment of compliance with various sub-articles of Article 5.

Sub-article 5.1. No advertising or other form of promotion to the general public of products within the scope of this Code

The 856 women who were interviewed were asked if they had seen any promotions or messages about BMS products since the pregnancy began or since the child was born. This was divided into two sections: electronic media and physical media.

The sources that the women most frequently recalled as seeing advertising for covered BMS products were television (84.5%), shop or pharmacy (19.9%), and magazine (5.6%). In contrast, the two least frequently mentioned sources were health facilities (1.5%) and radio (2.1%). We are

uncertain about the reliability of the data on television advertising, since our independent media monitoring (see Table 5) identified only 22 television advertisements for products covered by The Code, and the majority of those were for formula products for children 12-24 months old or a specific formula product was not specified. There were also advertisements observed for formula products for children of 2 years or older. It is possible that some women were recalling those advertisements, and it is also possible that they recalled advertisements from an earlier period of time. This could similarly affect the reported frequency of seeing advertisements from other sources.

The companies mentioned most frequently over all sources were Danone, Nestlé, and Friesland Campina. Although it was not possible for women to recall specific products by age range most of the time, some products were identified by the women, as listed in Table 4b.

Table 4a. Women's recall in interviews related to article 5.1: No advertising or promotion to the general public

N = Company	856	# Mentions	% Mentions
Danone	Television	582	68.0%
	Internet	17	2.0%
	Social Media	11	1.3%
	Magazine	24	2.8%
	Shop/pharmacy	81	9.5%
	Billboard	14	1.6%
	Other	45	5.3%
	TOTAL	774	NA
Nestlé	Television	411	48.0%
	Internet	9	1.1%
	Social Media	7	0.8%
	Magazine	17	2.0%
	Shop/pharmacy	74	8.6%
	Billboard	13	1.5%
	Other	22	2.6%
	TOTAL	553	NA
Friesland Campina	Television	118	13.8%
	Internet	0	0.0%
	Social Media	3	0.4%
	Magazine	4	0.5%
	Shop/pharmacy	23	2.7%
	Billboard	3	0.4%
	Other	12	1.4%
	TOTAL	163	NA

Table 4a. Women's recall in interviews related to article 5.1: No advertising or promotion to the general public (continued)

N = Company	856	# Mentions	% Mentions
Morinaga	Television	37	4.3%
	Internet	1	0.1%
	Social Media	0	0.0%
	Magazine	2	0.2%
	Shop/pharmacy	6	0.7%
	Billboard	0	0.0%
	Other	2	0.2%
	TOTAL	48	NA
Mead Johnson	Television	19	2.2%
	Internet	1	0.1%
	Social Media	0	0.0%
	Magazine	1	0.1%
	Shop/pharmacy	6	0.7%
	Billboard	1	0.1%
	Other	4	0.5%
	TOTAL	32	NA
Pigeon	Television	23	2.7%
	Internet	0	0.0%
	Social Media	1	0.1%
	Magazine	2	0.2%
	Shop/pharmacy	6	0.7%
	Billboard	0	0.0%
	Other	0	0.0%
	TOTAL	32	NA
Others	Television	36	4.2%
	Internet	2	0.2%
	Social Media	0	0.0%
	Magazine	3	0.4%
	Shop/pharmacy	10	1.2%
	Billboard	3	0.4%
	Other	6	0.7%
	TOTAL	59	NA
TOTAL	Television	1226	NA
	Internet	30	NA
	Social Media	22	NA
	Magazine	53	NA
	Shop/pharmacy	206	NA
	Billboard	34	NA
	Other	91	NA
	TOTAL	1661	NA

Table 4b. Sample of brands/products named, by company

Company	Brand/product
Danone	Bebelac, Bebelac 3, Bebelove 1, Nutrilon, SGM Presnutri
Nestlé	Dancow 1+, Dancow Batita, Lactogen, S26
Friesland Campina	Frisian Flag, Frisian Flag Jelajah 123, Friso
Mead Johnson	Enfagrow, Sustagen

Identification of advertising related to BMS products was also done directly by media monitoring. For this purpose, we determined what were likely to be the most frequent carriers of advertisements, based on reported overall advertising spending by medium in Indonesia. The two media with the most advertising expenditure were television and newspapers. We expanded this by including new online sources, such as online newspapers, internet sites, and social media. A professional media monitoring service, Nielsen, was hired to monitor advertising as described in the methodology chapter. This was done for three months, May, June and August 2015. In addition, the local study team monitored BMS manufacturer websites, Facebook, and YouTube for the entire month of August 2015.

Results from the media monitoring are presented in Table 5. Overall, the media monitoring conducted by the professional monitoring service and our own monitoring team identified what we defined as 495 unique advertisements during this time period, many of which ran multiple times or on multiple outlets, such as several television stations. This is heavily skewed by internet and social media-related advertisements (417 of the 495 total ads, or 84.2%). Although the women reported hearing about the BMS products most frequently by television, we were able to identify only 39 unique TV advertisements. It is also surprising that only 5.6 percent of the women reported hearing about products by internet or social media, despite the large number of ads that we identified from those sources.

Table 5. Observations related to sub-article 5.1: No advertising or promotion to the general public media monitoring, by advertiser and product type

Company	Type of product	Medium						
		Unique ads	Television	Print newspapers	Internet	Facebook	Twitter	YouTube
Nestlé	Infant Formula	6			6			
	Follow-on Formula	5			5			
	Growing-up Milk	162	9	13	31	67	20	22
	TOTAL	173	9	13	42	67	20	22
Danone	Infant Formula	18			18			
	Follow-on Formula	4			4			
	Growing-up Milk	87	19	14	20	26	8	
	TOTAL	109	19	14	42	26	8	0
Mead Johnson	Infant Formula	8			8			
	Follow-on Formula	4			4			
	Growing-up Milk	66	2	2	19	19	19	5
	TOTAL	78	2	2	31	19	19	5
Morinaga	Infant Formula	8			3	5		
	Follow-on Formula	1				1		
	Growing-up Milk	22	2	0	4	6	10	
	TOTAL	31	2	0	7	12	10	0
Friesland Campina	Infant Formula	4			4			
	Follow-on Formula	2			2			
	Growing-up Milk	24	4	10	10			
	TOTAL	30	4	10	16	0	0	0
Abbott	Infant Formula	3			3			
	Follow-on Formula	0						
	Growing-up Milk	17	3	0	14			
	TOTAL	20	3	0	17	0	0	0

Table 5. Observations related to sub-article 5.1: No advertising or promotion to the general public media monitoring, by advertiser and product type (continued)

Company	Type of product	Medium						
		Unique ads	Television	Print newspapers	Internet	Facebook	Twitter	YouTube
Fonterra	Infant Formula	3			3			
	Follow-on Formula	1			1			
	Growing-up Milk	4			4			
	TOTAL	8	0	0	8	0	0	0
Other (7 companies)	Infant Formula	2			2			
	Follow-on Formula	1			1			
	Growing-up Milk	3			3			
	Bottles	33			8	25		
	Teats	2			1	1		
	Pacifiers	5			1	4		
	TOTAL	46	0	0	16	30	0	0
ALL COMPANIES		495	39	39	179	154	57	27

Sub-article 5.2. Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code

Of the 856 women who were interviewed, 20 (2.3%) women said that they had received free samples of any BMS product from a manufacturer since the pregnancy began or the baby was born. Seventeen (17) of the women mentioned 20 different products. The results by type of product, most frequently mentioned companies, and product names are presented in Tables 6a and 6b.

Table 6a. Women's recall in interviews related to sub-article 5.2, no samples to pregnant women, mothers, or members of their families

N = Company	856	# Mentions	% Mentions
TOTAL	Infant formula	3	0.4%
	Follow-on formula	0	0.0%
	Growing-up Milk	14	1.6%
	Formula, not specified	2	0.2%
	Complementary food (0-6 months)	0	0.0%
	Bottles, teats, pacifiers	1	0.1%
	TOTAL	20	2.3%
Nestlé	Infant formula	1	0.1%
	Follow-on formula	0	0.0%
	Growing-up Milk	7	0.8%
	Formula, not specified	1	0.1%
	Complementary food (0-6 months)	0	0.0%
	Bottles, teats, pacifiers	0	0.0%
	TOTAL	9	1.1%
Friesland Campina	Infant formula	0	0.0%
	Follow-on formula	0	0.0%
	Growing-up Milk	4	0.5%
	Formula, not specified	1	0.1%
	Complementary food (0-6 months)	0	0.0%
	Bottles, teats, pacifiers	0	0.0%
	TOTAL	5	0.6%
Danone	Infant formula	2	0.2%
	Follow-on formula	0	0.0%
	Growing-up milk	1	0.1%
	Formula, not specified	0	0.0%
	Complementary food (0-6 months)	0	0.0%
	Bottles, teats, pacifiers	0	0.0%
	TOTAL	3	0.4%
Abbott	Infant formula	0	0.0%
	Follow-on formula	0	0.0%
	Growing-up Milk	1	0.1%
	Formula, not specified	0	0.0%
	Complementary food (0-6 months)	0	0.0%
	Bottles, teats, pacifiers	0	0.0%
	TOTAL	1	0.1%

Table 6a. Women's recall in interviews related to sub-article 5.2, no samples to pregnant women, mothers, or members of their families (continued)

N = Company	856	# Mentions	% Mentions
Morinaga	Infant formula	0	0.0%
	Follow-on formula	0	0.0%
	Growing-up Milk	1	0.1%
	Formula, not specified		
	Complementary food (0-6 months)	0	0.0%
	Bottles, teats, pacifiers	0	0.1%
	TOTAL	1	0.2%
Pigeon	Infant formula	0	0.0%
	Follow-on formula	0	0.0%
	Growing-up Milk	0	0.0%
	Formula, not specified	0	0.0%
	Complementary food (0-6 months)	0	0.0%
	Bottles, teats, pacifiers	1	0.1%
	TOTAL	1	0.1%

Table 6b. Sample of brands/products named by women, by company

Company	Brand/product
Nestle	Dancow, Dancow 1+
Friesland Campina	Frisian Flag, Frisian Flag Jelajah 123
Danone	Nutrilon

NOTE: 6 women also reported receiving a sample from a shop or pharmacy.

For those who reported receiving growing-up milk, it is not clear for whom this product was intended, or if the products may have been misidentified. Only one woman mentioned receiving complementary food, bottles, teats or pacifiers.

No company was mentioned by more than 9 women, or 1.1 percent of the respondents.

The women's self-reports suggest that there may still be some non-compliance with The Code on providing samples to women, but the incidence is low. It was not possible to determine through this survey protocol whether this is associated with individual sales representatives acting on their own initiative, or whether this reflects weaknesses in companies' management systems. It is also not possible for us to tell from the data if these products were intended for a different child or as a reminder for the future, since most of those mentioned were growing-up milk.

Sub-article 5.3. For products within the scope of this Code, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level

Data to assess compliance with this sub-article were collected by visiting retail outlets within 1 kilometer of each of the health facilities that participated in the study. A total of 111 retail outlets (3 per health facility) were visited. These retailers were selected so as to maximize the possibility that they might sell enough BMS products to offer sales promotions. The goal was to select one BMS specialty store, one supermarket or hypermarket, and one chain store around each health facility. When this was not possible, a different type of store was selected. For the most part, these other retail outlets were smaller grocery stores. In practice, more chain stores were studied than any other type of store.

The results of the study of the 111 retail outlets are presented in Tables 7a, 7b, and 7c. Overall, promotions were identified in 94 (84.7%) of the outlets. This was driven by the chain stores (100%) and the supermarkets/hypermarkets (91.7%).

Table 7a. Observed point-of-sale promotions related to sub-article 5.3

Type of store	Total stores	# of "Yes" responses	% "Yes" responses
Total stores	111	94	84.7%
Type of store			
BMS Specialty Stores	26	13	50.0%
Supermarkets/Hypermarkets	24	22	91.7%
Chains	57	57	100.0%
Other	4	2	50.0%
	111	94	84.7%

Table 7b. Observations of type of promotions related to sub-article 5.3

Type*	Number
Shelf tag/talker	6
Poster	2
Display unit	15
Discount	28
Coupons	12
Gifts	76
Live sales representative	9
Other	18

* A single promotion may include more than one type. The total number in Table 7b may exceed the total in Table 7a.

Table 7c. Observations of point-of-sale promotions related to sub-article 5.3

Company	Infant formula	Follow-on formula	Growing-up milk	Formula, Not specified	Complementary food	Bottles	Teats	Pacifiers	Unknown	Total	average per outlet
Danone	5	2	195	8	0	0	0	0	0	210	1.89
Nestle	3	0	137	17	0	0	0	0	0	157	1.41
Friesland Campina	1	1	52	7	0	0	0	0	0	61	0.55
Morinaga	1	0	49	0	0	0	0	0	0	50	0.45
Pigeon	0	0	0	0	0	16	20	7	5	48	0.43
Huki	0	0	0	0	0	21	13	6	2	42	0.38
Mead Johnson	0	0	35	6	0	0	0	0	0	41	0.37
Abbott	0	0	18	0	0	0	0	0	0	18	0.16
Tempo Scan	0	0	10	0	1	0	0	0	0	11	0.10
Dr. Brown's	0	0	0	0	0	2	0	0	2	4	0.04
Fonterra	0	0	2	1	0	0	0	0	0	3	0.03
Philips Avent	0	0	0	0	0	1	0	1	1	3	0.03
Disney Baby	0	0	0	0	0	2	0	0	0	2	0.02
Nuk	0	0	0	0	0	1	0	1	0	2	0.02
Total	10	3	498	39	1	43	33	15	10	652	5.87

The companies whose brands or products were most frequently promoted were Danone and Nestlé.

Sub-article 5.4. Manufacturers and distributors should not distribute to pregnant women or mothers of infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding

Of the 856 women interviewed, 101 (11.8%) reported receiving a gift from someone other than a family member or friend. Most of these women (77) received the gifts from health professionals, often in the hospital of clinic. Many mentioned goodie bags, shampoos, and similar non-BMS gifts, and only two mentioned a BMS company name. Only 24 women mentioned receiving a gift from a shop, pharmacy, or BMS company representative, and again most of the gifts described appear to be non-covered products.

Sub-article 5.5. Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children

Non-compliance with this sub-article was based on a question in the women's interview about whether anyone had spoken with them about BMS products. For purposes of this analysis, both company representatives and shops/pharmacies, acting as retail distributors of the products, were considered.

The results related to this sub-article are presented in Tables 8a and 8b. Of the 856 women interviewed, 25 (2.9%) reported having been spoken to by a company representative about BMS products. Fourteen (14, 1.6%) reported having spoken with a company representative, and the other eleven (1.3%) reported having such a conversation with a person at a shop or pharmacy. All 25 women said that a particular brand or product had been recommended, and one woman mentioned two different companies. The companies most frequently mentioned were Danone, Fonterra, and Nestlé.

Table 8a. Women's recall of contacts related to sub-article 5.5, marketing personnel should not seek direct or indirect contact with pregnant women or mothers of infants and young children

N=856	# of "Yes" responses	% "Yes" responses	# of "Yes" responses	% "Yes" responses
Type of representative	**Company representative**		**Shop/pharmacy**	
Company				
Danone	7	0.8%	5	0.6%
Fonterra	2	0.2%	2	0.2%
Nestlé	2	0.2%	2	0.2%
Friesland Campina	0	0.0%	2	0.2%
Mead Johnson	1	0.1%	1	0.1%
Morinaga	2	0.2%	0	0.0%
	0	0.0%	0	0.2%
Total	14	1.6%	12	1.4%

* **NOTE:** The sum of mentions for all companies combined may exceed the Total women mentioning a company, since some mentioned more than one company.

Table 8b. Sample of brands/products named by company

Company	Brand/product
Danone	Bebelove, Bebelac, SGM (numerous)
Fonterra	Anmum
Nestlé	S26 Gold, Lactogen, Dancow
Mead Johnson	Enfamil, Enfamil A+ Tahap 2
Friesland Campina	Frisian Flag

While the women's recall of level of contact by company representatives is relatively low, specific BMS products appear to be recommended. The larger problem, though, seems to come from conversations with family members and friends. While this is not covered by The Code, 192 (22.4%) reported having a conversation about BMS products with a family member or friend. Although they less frequently recommended specific products (160, 83.3%), women receive far more information about BMS products from these sources.

C. Article 6: Health Care Systems

Data were collected to allow assessment of compliance with the following sub-articles of Article 6.

Sub-article 6.2. No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code

Possible non-compliance with the provisions this sub-article were identified through two sources: (1) women reporting that a healthcare worker had spoken to them about using BMS products and (2) healthcare workers reporting that a company representative had visited the facility for the purpose of talking to women, obtaining contact information for women, providing materials for women, or distributing samples to women. The results related to possible non-compliance with this sub-article are presented in Tables 9a and 9b.

Overall, 47 (5.5%) of the 856 women reported being spoken to by a health professional about using BMS products, and 39 (83.0%) of those professionals reportedly recommended a specific product. The most frequently mentioned companies were Nestlé (18), Danone (14) and Friesland Campina (3).

Table 9a. Women's recall in interviews of recommendations by health professional covered by sub-article 6.2: No facility of a healthcare system should be used for purposes of promoting products within scope of code

Type of representative		# of "Yes" responses	% "Yes" responses
N = 856			
Health Professional			
Total Mentioned by Women		47	5.5%
Recommended Product		39	4.6%
Brands Recommended*	Nestlé	18	1.9%
	Danone	14	1.6%
	Friesland Campina	3	0.4%
	Morinaga	1	0.1%
	Pigeon	1	0.1%
	Can't Remember	3	0.4%

* One woman mentioned two companies.

Table 9b. Healthcare workers recall in interview of company representative visits that may be covered by sub-article 6.2: No facility of a healthcare system should be used for purposes of promoting products within the scope of The Code

	Number	Percent
Number of Health Facilities	37	100%
Number with at least one health worker responding that company rep visited to contact women	10	27.0%
Number with at least one health worker responding that company rep visited to distribute samples	4	10.9%
Companies most frequently mentioned		
Scaling Up Nutrition (SUN)	4	10.8%
Danone	3	8.1%
Friesland Campina	3	8.1%
Nestle	3	8.1%
Mead Johnson	1	2.2%
Can't Remember	3	8.1%

From the interviews with healthcare workers, at least one worker at 10 of the 37 facilities (27.0%) reported that a company representative had visited with the intent of talking to women, obtaining contact information for women, or providing materials for women. The most frequently mentioned companies/organizations were SUN (4), Danone (3), Friesland Campina (3), and Abbott (3) and Nestlé (3). For 4 (10.8%), the representative reportedly wanted to distribute samples to the women. We do not know if the representatives were allowed to do so. We are also uncertain of the role of SUN,[16] which is a government-supported international non-profit organization dedicated to improving the nutrition of children in the first 1,000 days of life. One healthcare worker reported that the SUN representative wanted to distribute samples.

Sub-article 6.3. Facilities of health care systems should not be used for the display of products within the scope of this Code, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor

This sub-article was addressed as part of the analysis of Sub-article 4.2, Informational and Educational Materials, where any placards and posters were also identified. As noted above, 24 items of informational materials from BMS manufacturers were found on public display in 12 of the 37 health facilities. Interviewers and supervisors were asked to observe any areas of the facility that

[16] scalingupnutrition.org.

were open to them, but they did not attempt to see closed areas, such as private offices or locked spaces.

Sub-article 6.8. Equipment and materials, in addition to those referred to in Article 4.3, donated to a health care system may bear a company's name or logo, but should not refer to any proprietary product within the scope of this Code

We identified no instances of donations covered by this sub-article. Interviewers and supervisors were asked to observe any areas of the facility that were open to them, but they did not attempt to see closed areas, such as private offices or locked spaces.

D. Article 7: Health Workers

Data were collected to allow assessment of compliance with the following sub-articles of Article 7.

Sub-article 7.2. Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle feeding is equivalent or superior to breast-feeding

Possible non-compliance with this sub-article was partially addressed by the interviews with the healthcare workers. Only two workers from the 37 facilities stated that a company representative had visited to give product information to health professionals.

Sub-article 7.3. No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families

From the healthcare workers' interview responses, we did not detect the provision of any substantial gifts, such as clothing, money, paid attendance at a general conference or meeting, or paid attendance at a company-sponsored event. Only one worker out of the 127 interviewed mentioned any gift at all. As with other items that a worker might consider inappropriate, it is possible that there could be some underreporting because of the interviewers' neutral probing approach.

Sub-article 7.4. Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level, and health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families

None of the 127 healthcare workers who were interviewed mentioned receiving samples from a BMS manufacturer.

E. Article 9: Labelling

As specified in the IGBM Protocol, data were collected to allow assessment of compliance with the following sub-articles of Article 9.

Sub-article 9.2. Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the points … (see Supplemental Table A in Appendix L)

This sub-article addresses 5 requirements for labelling, as shown in Supplemental Table A. We also added the local regulation's required wording that "Infant Formula Milk is not a Sterile Product; therefore, read the Preparation Instructions" must be on the main part of the label with font size at least 2mm. Overall, the labels (and inserts, if available) of 98 infant formula, follow-on formula, growing-up milk, or complementary food were analyzed. Apparent non-compliance was relatively common, with the most frequent recorded observations being (1) statement that product should be used only on advice of a healthcare worker; (2) lack of instructions on appropriate preparation and health hazards of inappropriate preparation and (3) pictures that idealize use of infant formula. Determining whether pictures on a product constitute non-compliance generated much discussion. Some stakeholders believe that only human pictures should be prohibited; others believe that any picture of happy creatures, whether human, animal, or some other characters, should not be used. For purposes of this study, we counted pictures of all types, but we present the data separately for human vs. other pictures in Supplemental Table A. Of the 63 products that were coded as having

pictures idealizing BMS (one product was in both categories), approximately 72% had pictures of animals or other characters only and 28% of these products had pictures of humans.

We have analyzed the data by number of products examined for each company so that we could calculate an average number of observations per product (see Table 10).

Sub-article 9.3. Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant

The IGBM protocol does contain an item that addresses this point, but the interpretation is not completely clear. Therefore, we are not reporting on this sub-article.

Sub-article 9.4. The label of food products within the scope of this Code should also state all of the points (See Supplemental Table B, Appendix L)

This sub-article addresses 5 additional requirements for labelling, as shown in Supplemental Table B, plus we added 2 items that are only mentioned at the beginning of the International Code's labelling article (easy to read and appropriate language) without specifically being defined in the list of requirements. Further, for formula products and complementary foods, we added the local regulation's requirements that (1) all ingredients used are listed in order from the highest to lowest amount, either horizontally or vertically; and (2) that net weight or net content be included. There was no observed non-compliance with the net weight/net content requirement, so it is not shown in the tables.

As with Sub-article 9.2, overall the labels (and inserts, if available) of 98 infant formula, follow-on formula, growing-up milk, or complementary food products were analyzed. Observations were less common, with almost no non-compliance with any of these requirements.

Table 10. Type and number of observations of non-compliance related to labelling, by company

Company	Number of products assessed	Total observations	Average Number of observations per Product	Words "Important Notice" or equivalent	Statement that should be used only on advice of health worker	Instructions on appropriate preparation	Formula not sterile product	No pictures that idealize use of infant formula - human pictures	No pictures that idealize use of infant formula - other pictures	Terms "humanized", "maternalized" or similar should not be used	Ingredients used	Composition/analysis of product	Storage conditions required	Batch number	Expiration date, taking into account local climate and storage conditions	Easily readable	Written in appropriate language	Ingredients in order
Danone	27	67	2.5	1	8	12	9	6	17	8	0	0	1	0	0	0	0	5
Fonterra	3	8	2.7	0	2	2	2	1	1	0	0	0	0	0	0	0	0	0
Morinaga	9	22	2.4	0	3	3	3	4	4	3	0	0	0	0	0	0	0	2
Nestlé	23	46	2.0	0	11	5	7	5	11	5	0	0	0	0	0	0	1	1
Friesland Campina	6	15	2.5	0	2	2	2	1	2	3	0	0	0	0	0	0	0	3
Mirota	2	5	2.5	0	1	2	1	0	1	0	0	0	0	0	0	0	0	0
Mead Johnson	10	9	0.9	0	1	1	1	0	5	1	0	0	0	0	0	0	0	0
Abbott	8	9	1.1	0	1	0	2	0	5	1	0	0	0	0	0	0	0	0
Tempo Scan	1	3	3.0	0	1	1	0	1	0	0	0	0	0	0	0	0	0	0
Heinz	8	5	0.4	NA	NA	NA	NA	0	0	0	0	2	0	0	0	0	NA	3
CV Trinitas	1	0	0.0	NA	NA	NA	NA	0	0	0	0	0	0	0	0	0	NA	0
Total	98	189	1.9	1	30	28	27	18	46	21	0	2	1	0	0	0	1	14
Percent				1.0%	30.6%	28.6%	27.6%	18.4%	46.9%	21.4%	0.0%	2.0%	1.0%	0.0%	0.0%	0.0%	1.0%	14.3%

Conclusions and Recommendations 6

This report is based on a study carried out for ATNF on a pilot basis. It is one of several in recent years to follow the 2007 IGBM Protocol[17], and one of the first to publish its results. While this pilot study did have some limitations (as discussed in Chapter 7), it does provide valuable population-based estimates of compliance with the International Code, and it can serve as a model for similar studies in other countries or in other populations, such as non-urban populations. The methodology of the IGBM Protocol can serve as a valuable complement to other approaches to monitoring compliance with The Code, such as the surveillance approach employed by IBFAN globally.

Conclusions About Compliance with The Code and National Regulations

Companies' Cross-Marketing of Products. The most substantial area of recalled non-compliance by women in their interviews, and one of special concern, may be advertising (Sub-article 5.1). As noted in Chapter 5, the vast majority of the women interviewed reported hearing or seeing a relevant advertisement during the pregnancy or since the baby was born. Our media monitoring service, though, identified few relevant advertisements on television, but most of them were aired many times. We are not able to reach a clear conclusion about the women's reports of television advertising, since most of the TV advertisements that our media monitoring service identified were for products beyond the scope of The Code. This is of concern, since it is possible that many women may be familiarized with the names of the BMS manufacturers and their brands through the advertisements for non-covered products (such as formula for children who are 2+ years old) that are of the same brand as covered products. This is especially probable since the labelling of the covered products frequently is nearly identical to that of the products for children who are 2+ years old.

Point-of-Sale Promotions. The second most frequent area of observed non-compliance was in promotions at point-of-sale retail outlets (Sub-article 5.3). Of the 111 retail outlets that the study team visited, promotions were observed in 94 (84.7%). Because the sample of outlets was a

[17] The IGBM Protocol has been used to carry out assessments in Bangladesh, Botswana, Kenya, Poland, South Africa, Thailand, Uganda, and possibly other countries.

purposive sample of the types of stores that we thought would be most likely to have promotions, we cannot say that this estimate is representative of the total retail community in Jakarta. Nonetheless, the number of promotions was substantial. Thus, this should be considered an area of major concern. Our information does not allow us to identify the extent of the role of each manufacturer in these promotions– either in shops or by online retailers, but companies should ensure that distributors and retailers are aware of their responsibilities under The Code.

Definition of 'Idealizing'. The third most considerable area for which observed non-compliance was identified was product labelling (Sub-articles 9.2 and 9.4). There are numerous provisions in these two sub-articles, and some level of non-compliance was documented for almost all of them. The most substantial, and perhaps most controversial, relates to pictures that might idealize the use of Breast-milk Substitutes. As was noted at the beginning of this chapter, there is no definition in The Code or elsewhere for what constitutes idealization, and there is debate over whether this should apply only to pictures of humans.

Contact by Company Representatives. Another area of concern is what is reported by women and healthcare workers as the continuing effort by some company representatives to make contact with pregnant women and mothers of infants. For 10 of the 37 health facilities (27%), at least one healthcare worker reported that a company representative had visited the facility to seek direct contact with women or to obtain contact information for them (Sub-article 6.1). The study data collection form does not go into sufficient detail to allow us to determine if the company representatives were successful. For Sub-article 6.1, 47 of the 856 women (5.5%) interviewed said that a health professional had spoken to them about using Breast-milk Substitutes.

Samples and Gifts. Approximately 7 percent of the women reported receiving a gift from someone other than a family member or friend, but it appears that most of these gifts were from healthcare workers, particularly as congratulatory gifts from clinic personnel or other people who did not work for a BMS manufacturer.

A summary of observed non-compliance for the top 10 producers of covered formula and complementary food products found in Indonesia is presented below. Since the number of points of non-compliance varies by Sub-article and their relative importance may differ, this is presented for descriptive purposes only.

Executive Summary Table: Observations of Non-Compliance By Article and Source

Company	Number of formula and complementary food products in study	Total observations	Relevant sub-article			
			4.2 Facility/ store observation	5.1 Media monitoring	5.3 Store observation	9.2 and 9.4 Label analysis
Danone	27	356	12	109	210	25
Nestlé	23	357	8	173	157	19
Mead Johnson	10	127	3	78	41	5
Friesland Campina	6	101	6	30	61	4
Kalbe Morinaga	9	88	0	31	50	7
Abbott	8	46	1	20	18	7
Fonterra	3	14	0	8	3	3
Heinz	8	3	0	0	0	3
All others (4)	4	28	8	6	11	3
Total	98	1,120	38	455	551	76

Conclusions About The Code and The IGBM Protocol

Definitions of Non-Compliance. The International Code includes a complex set of recommendations, some of which can be challenging to interpret or measure. For example, the prohibition against pictures that idealize the use of Breast-milk Substitutes is not defined, and as was noted in Chapter 5, it is a subject of considerable debate. Other examples of areas that present some difficulties in defining or measuring non-compliance are what constitutes an inducement to a health worker to promote BMS products or what is considered advertising in a global internet age.

The IGBM Protocol is Good but in Need of Updating. As stated earlier, the IGBM Protocol was selected by ATNF to assess compliance by BMS manufacturers with the recommendations of The Code because this Protocol is seen as the best existing rigorous research-oriented approach to conduct such an assessment. Indeed, the IGBM Protocol does a very good job of carefully considering most of the Articles of The Code that apply in some way to manufacturers, and it establishes a sophisticated approach to collecting data from numerous sources in order to best address each sub-article. This includes direct interviews with pregnant women and mothers of infants who attend health facilities, direct interviews with health care workers in those same facilities, physical observation and analysis of BMS manufacturer-provided infant feeding informational materials in the same facilities and retail outlets, physical observation of point-of-sale promotions in various types of retail outlets around the health facilities, analysis of product labels and inserts, and monitoring of various communications media to identify advertising of BMS products. This represents six different sources of information captured by different methodologies. Further, the

sampling approach to selecting clinics, women, and health care workers makes the study representative of the general population in the study area for facilities, pregnant women and mothers of infants, and health care workers in clinics that see eligible women.

With its six sources of data collection, the IGBM protocol addresses a great number of the sub-articles of Articles 4, 5, 6, 7, and 9 of the International Code. In summary, we were able to assess compliance with 16 sub-articles of The Code. This addresses all of the sub-articles that apply to BMS manufacturers, with the exception of those in Article 8, which deals with prohibitions on outside activities by representatives of BMS manufacturers.

A notable modern change was the appearance of advertisements for covered products appearing on the Internet, on Facebook, Twitter, and YouTube. These sources were not a focus of the IGBM protocol, which was last updated in 2007, but this is something to which much more attention should be paid in the future. With respect to Sub-article 4.2, we were able to identify 38 items that were considered printed informational or educational material from BMS manufacturers. Hard-copy approaches appear to be less emphasized than they may have been in the past.

Finally, The Protocol does not capture information on some requirements that were issued around the time of its last update or later, and it would be useful to update The Protocol to include these items. One such requirement is examining labels for a warning to the effect that dried powdered infant formula is not a sterile product and may contain harmful microorganisms as per WHA 58.32 (2005). This has been incorporated into the Indonesia regulations. Also there is no mention of free and low cost supplies. WHA 47.5 prohibits free and low cost supplies of products under the scope of the Code in any part of the health care system. WHA63.23 prohibits nutrition and health claims for foods for infants and young children in product labeling. There are other newer provisions that could be added to The Protocol.

Recommendations

For Companies with Respect to Product Marketing. BMS manufacturers should work to strengthen corporate policies and close loopholes in management procedures that may have given rise to interview-reported or observed non-compliance with The Code and with local regulations. The most important issue is promotion of covered products in retail outlets. While advertising most likely involves corporate level decisions and input, sales promotions may be developed locally, and it

is less clear whether the actions of sales representatives reflect corporate decisions or are the independent decisions of individual representatives. Additional focus should be on the proper training of local company representatives regarding what their obligations and restrictions are under The Code and local regulations. Further, the manufacturers should take all reasonable steps to ensure that their distributors and retailers understand their obligations under The Code and local regulations.

We also recommend that formula manufacturers consider changing product branding and packaging to clearly differentiate products for different age groups, children from 0-24 months old versus children who are 2 years or older. This might prevent confusion among women, who may see an advertisement for a product for older children and not understand the difference between it and products of the same brand for younger children. A new regulation (Number 49 of 2014) due to come into force in February 2017 introduces new quality and labeling requirements for growing-up milk products and restricts their advertising by preventing manufacturers from using the same trade name as the trade names of infant formula and follow-on formula.

Manufacturers should also extend commitments to online marketing of products, and they should pay increased attention to products sold by online stores. While we observed a number of these stores in our search for advertising, the study was not set up to evaluate their activities. We did identify a number of advertisements for covered products through these on-line stores. This is a development about which very little is known.

For WHO and Governments. Future efforts to promote BMS manufacturers' compliance with The Code should focus in particular on online advertising and use of social media. These media have changed the face of advertising, and they also have global reach, since they can be accessed by women from many different countries, not just those in a single country. This is a problem that may be very difficult to control.

Education of the Public. This study was about BMS manufacturers' compliance with the International Code and local Indonesian regulations, but from a public health perspective, we also identified other important issues that have an impact on whether a woman chooses to use a Breast-milk Substitute. Efforts to better educate the population as a whole, or to give more directed advice about exclusive breastfeeding to a pregnant woman, as many countries and organizations are already doing, should help to increase breastfeeding rates.

Strengthen Definitions of Terms. We have mentioned a number of times that there are a number of gray areas concerning how to interpret parts of The Code. Although it is unlikely that a revised version of The Code with more precise definitions can be produced, further directives from the WHO or other organizations on unclear areas would be helpful. One particular example related to labeling is what types of pictures are considered as idealizing BMS, especially whether only human pictures fit this definition, or whether pictures of animals and other non-human creatures should also be considered non-compliant. A universally-accepted definition would be very valuable.

7 Limitations of the Pilot Study

As has been noted several times previously, this pilot study followed the IGBM Protocol and data collection forms. The IGBM Protocol does a very good job of addressing nearly all of the sub-articles in the International Code that apply to manufacturers. Nonetheless, there are limitations to the study and how the results from it should be interpreted and acted on by users.

A. Recall Bias

The most significant limitation of the study is that much of the information needed to assess compliance comes from interviews with women and with health care workers. In any interview situation, self-reported events or information can be misreported because of incorrect recall, misunderstanding, reluctance to provide complete information, or a perception of what the respondent thinks the desired response should be. When a period of recall is involved, as was the case with both the women and the health care workers, there can also be recall bias that may involve telescoping a remembered event into the recall period, even though it occurred outside of it, or of microscoping an event outside of the recall period when it actually occurred inside of it. We believe that the questions we asked were clear and objectively written, with no suggestion about what answer was desired. The interviewers were also carefully trained not to use leading probes and not to assume an answer if the respondent did not give it completely. The one topic that was possibly misinterpreted by the women was advertising of covered products, as has been discussed in Chapters 5 and 6. Recall bias and incorrect memory are potential cautions when interpreting the data. Where the interviews identify only a very small number of possible incidents of non-compliance, the information should be used very cautiously, since they could be recall errors. On the other hand, when many episodes are reported, one should generally be confident in accepting that a substantial amount of non-compliance did occur (with the noted exception of television advertising), even if there are some recall errors. The exact percentage estimate is less important that the obvious magnitude of the problem.

B. Selection of Healthcare Workers

A second limitation of the study is that while healthcare workers were randomly selected within each health facility, they might not be the best workers to interview with respect to facility-related issues. The healthcare worker interview has one section that is directly related to the worker; the other sections are facility-level questions. For these questions, the most knowledgeable respondents might be the facility manager and the facility financial manager. The study's approach might have resulted in under-reporting of certain items, such as equipment donation and visits by sales representatives.

C. Selection of Retail Outlets

A third limitation is related to the selection of retail outlets to observe point-of-sale promotions. This selection was purposive, not representative. The objective was to select stores that were judged most likely to have such promotions so that promotions could be documented if they were occurring. The percentage of stores that had at least one promotion was very high, but this cannot be extrapolated to the universe of stores in Jakarta. Further, each store was visited on only one day, so it is possible that more stores would have had promotions if they had been visited over a period of time.

D. Population of Women Studied

Because the sample was limited to mothers with children only up to 6 months old, the Protocol also does not address the promotion of breastfeeding up to 24 months of age for the children, and consequently may underestimate promotion of BMS products for older children.

E. Other Limitations

Other limitations include the lack of precise definitions for some of the items that needed to be assessed and the lack of sufficient data collection to address a few areas. A number of situations were noted as "gray areas", where it was not clear if something should be considered non-compliance. In such situations we have been cautious about over-interpreting the information.

Several examples are cited in Chapter 5, such as whether gifts to health care workers or gifts to women might influence their promotion or use of BMS products.

This pilot study was a one-time cross-sectional survey that provides reasonable prevalence estimates for the point in time that it was conducted. There is currently no ability to monitor changes over time, or to provide continuous surveillance, such as is done by IBFAN. Follow-up studies in the same geographic area could make the results from this pilot study a valuable baseline to measure improvements or declines over time in compliance.

The focus of the IGBM protocol is on BMS manufacturers' compliance with the International Code and local regulations. It does not address whether the women chose to use a BMS product at some point, nor does it attempt to estimate what proportion of the women claimed to be exclusively breastfeeding.

Finally, this study was restricted to only 10 sub-districts urban Jakarta. The results should be representative for this area, but they should not be interpreted to apply to all of Indonesia. We believe that promotion of BMS products is likely to be highest in an urban area such as Jakarta because of the high density of the population and the ease of reaching women, but we have no evidence from other urban areas or rural areas of Indonesia to confirm this belief. These study results should be interpreted as applying only to urban Jakarta.

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