

Infant and Young Child Feeding & Human Milk Banking Guidelines 2015



**Formulated & Recommended by
Infant and Young Child Feeding (IYCF) Chapter of
Indian Academy of Pediatrics (IAP) &
Human Milk Banking Association**

President: Dr. R K Aggarwal

Secretaries: Dr. Satish Tiwari, Dr. Jayant Shah & Dr. Alka Kuthe

Project Incharge: Dr. Balraj Singh Yadav & Dr. Ketan Bharadva

Conveners: Dr. Vishesh Kumar & Dr. M J Khan



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NUTRITION FOUNDATION OF INDIA

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MESSAGE

For millennia, everywhere in the world, human breast milk has been the foundation for infant nutrition, survival and growth. The early half of the 20th century saw growing concern, especially among scientists in developed countries, about whether milk secretion by undernourished mothers in developing countries would be adequate to support infant growth. I carried out several studies out in the 1950s and 1960s which clearly showed that undernourished women continue to breast feed their offspring up to and even beyond two years of age. Neither the quantity of breast milk nor its quality in respect of macronutrients was adversely affected by maternal undernutrition.

Studies carried out by the National Institute of Nutrition, Hyderabad, in the 1970s clearly showed that breast feeding promotes optimal growth, protects against infection and provides some protection against pregnancy in the first six months when the baby is being solely breastfed. At the start of the current century, the WHO General Assembly adopted a resolution: "Breast milk is best". India has never needed convincing in this regard. Breast feeding remains a universal practice in all income groups in India. This has surely saved the lives of millions of children, and protected millions of others from morbidity and undernutrition, especially those from households living under conditions of poor environmental hygiene. However, eternal vigilance is required in order to ensure that optimal breast feeding practices continue, alongside efforts to improve maternal nutrition, complementary feeding practices and environmental hygiene. There are no short cuts, but the road map is very clear, and we should stay the course.

I am happy to see the effort put in by Dr. Satish Tiwari, Dr. Balraj Yadav, Dr. Ketan Bharadva, Dr. Vishesh Kumar, Dr. Pankaj Garg and Dr. Sarath Gopalan in this important initiative which is of utmost importance and practical relevance to India.

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Currently President, Nutrition Foundation of India, New Delhi

Preface

Justification:

Childhood malnutrition rates are high in the country with 43% children in India under five years reported to be underweight and 48% are stunted. Malnutrition in children is more an interplay of female illiteracy, ignorance about nutritional needs of infants and young children and poor access to health care. The National Rural Health Mission since its inception in 2005 endeavours to reduce Under Five mortality and has been implementing strategies through adopting a “Life Cycle” approach for breaking the inter - generational cycle of undernutrition. The steep rise in malnutrition in children during the first two years of life is indicative of poor infant feeding practices. Events leading to undernutrition often predate the birth of the child, maternal undernutrition, adolescent pregnancy, less spacing between births and high birth order resulting in birth of low birth weight babies. Appropriate feeding is crucial for healthy growth and development of the infant.

The year 2015, being the terminal year for the present MDGs as well as the year for shaping up the post 2015 development agenda, is of crucial importance in the development process around the Globe. It is the right time to assess our own progress vis-a-vis the Millennium Development Goals and these Guidelines are an attempt in that regard. So, there is need to revise the existing guidelines and to have more viable and scientifically accepted National Guidelines on Infant and Young Child Feeding.

Process:

To revise and update the existing IYCF 2010 guidelines, the IYCF chapter of Indian Academy of Pediatrics invited a group of experts for National Consultative Meet (through e-mail) for discussing and contributing on latest scientific advances and developments so as to formulate National IYCF guidelines 2015. Various partners from WHO, UNICEF, Ministry of Child Welfare Department, Ministry of Health and Family Welfare, Ministry of Chemical & Fertilizers of Govt of India, Human Milk Banking Association (of India), Indian Medico-Legal and Ethics Association, BPNI, SDHE Trust, various developmental partners and Academicians from various states of India contributed and drafted these guidelines.



Objectives:

To formulate, endorse, adopt and disseminate guidelines related to Infant & Young Child feeding from an Indian perspective (including Human Milk Banking, infant feeding in the HIV situation and Micronutrients).

Recommendations:

Appropriate and Optimal Infant and Young Child Feeding: Early initiation of breastfeeding, exclusive breastfeeding for the first six months of life followed by continued breastfeeding for up to two years and beyond with adequate complementary foods after completion of 6 months of age is the most appropriate feeding strategy for infants and young children. Micronutrient supplementation in infants, adequate nutrition and anemia control in adolescent girls, pregnant and lactating mothers is advocated. Concepts and need for human milk banks in India has also been incorporated.

Key Words:

Early Initiation, Exclusive breastfeeding, Appropriate complementary feeding, Hand washing, Malnutrition, Human Milk Banking, Micronutrients, HIV and Infant Feeding, IMS Act, IYCF in curriculum.

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IAP-IYCF CHAPTER





National Guidelines on Infant and Young Child Feeding 2015

The under five years population of India stands at a staggering 112.8 million (1). However, despite all the advances in health, education and agriculture sectors as well as vast improvements in the country's economy, India as of 2011, unfortunately figures in the list of countries that had made insufficient progress towards meeting the Millennium Development Goal (2). It has the largest numbers of under 5 children who are moderately or severely stunted (i.e., 61,723 thousands), accounting for 38% of the global burden. India also has the highest numbers of children with moderate and severe wasting (i.e., 25,461 thousands). An estimated 54,650 thousand children in this age group are underweight. India alone accounts for one third of the global burden of low birth weight even as 66% of infants in the country are not weighed at birth.

According to National Family Health Survey-3 data, about 20 million children are not able to receive exclusive breast feeding for the first six months of life and about 13 million do not get good, timely and appropriate complementary feeding after six months along with continued breast feeding. Over the past several years, India has failed to witness any remarkable progress in infant feeding practices, with only a small increment being recorded in exclusive breastfeeding rates amongst infants 0-6 months of age, from 41.2% in 1998-99 (NFHS-2) to 46.3% in 2005-2006 (NFHS-3). As per the NFHS-3 data 57% Indian mothers offered prelacteal feeds to their newborns, and around 45% do not start breastfeeding within twenty four hours of birth. The rate of early initiation of breastfeeding (within 1 hour of birth) stands abysmally low at 24.5%, while the median duration (months) of exclusive breastfeeding among last-born children is as brief as two months. Further, the rate of exclusive breastfeeding drops progressively from 51 percent at 2-3 months of age to 28 percent at 4-5 months of age. In a recent, largest Annual Health Survey conducted in India from 2010 to 2013 covering all the 284 districts (as per 2011 census) of 8 Empowered Action Group States like Bihar, Uttar Pradesh, Uttarakhand, Jharkhand, Madhya Pradesh, Chattisgarh, Odisha and Rajasthan (EAG States) and Assam, the percentage of children breast fed within one hour of birth was observed to vary from 30% in Bihar and Uttar Pradesh (UP) to

around 70% in Assam and Odisha. Children exclusively breastfed for at least 6 months ranged from 17.7% in UP to 47.5% in Chhattisgarh.

Complementary feeding is introduced in only 53% infants between 6–8 months of age, with only about 44 % of breastfed children being fed at least the minimum number of times recommended (3). Only half of them also consume food from three or more food groups. Feeding practices are even poorer in non-breastfeeding children. Overall, only 21 percent of breastfeeding and non-breastfeeding children are fed in accordance with the infant and young child feeding recommendations.

Some of the important reasons for the dismal nutrition status of our infants and young children include inadequate or inappropriate knowledge amongst caregivers regarding correct infant and young child feeding practices, frequent infections, high population pressure, low social and nutritional status of girls and women, suboptimal delivery of social services and lack of more viable infant and young child feeding guidelines.





Appropriate & Optimal Infant & Young Child Nutrition Practices

A. Technical Guidelines

1. Breastfeeding
2. Complementary feeding
3. Feeding in the context of HIV infection
4. Concept and Need for Human Milk Banks in India
5. Feeding in other specific situations
6. Micronutrients in Infant Feeding
7. Junk Food and Infant Feeding
8. Maternal Nutrition

B. Operational Guidelines

1. Recommendations for Governmental and International Agencies
2. Role of NGOs
3. Recommendations for the media
4. Training recommendations

A. Technical Guidelines

1. Breastfeeding:

WHO/UNICEF have emphasized the **first 1000 days** of life that is the 270 days in utero and the first two years after birth as the **critical window period** for IYCN (infant and young child nutrition) interventions. Because the maximal brain growth occurs in this period, malnutrition in this critical period can lead to stunting and suboptimal developmental outcome.

- a. Breastfeeding should be promoted to mothers and other caregivers as the **gold standard** feeding option for babies.
- b. **Pre-delivery counseling** individually or in groups organized by maternity facility or mother support group regarding advantages of breastfeeding and dangers of artificial feeding should prepare expectant mothers for successful breastfeeding.
- c. For all normal newborns (*including those born by caesarean section*) Skin-to-Skin contact should be initiated in about 5 minutes of birth in order that baby initiates breastfeeding in an hour of birth. This early contact should be continued till the first breastfeed is complete. The method of **“Breast Crawl”** can be adopted for early initiation (5). In case of operative birth, the mother may need motivation and support to initiate breastfeeding within the first hour. **Skin to skin contact** between the mother and new born should be encouraged by **‘bedding in the mother and baby pair’**. Mother should communicate, look into the eyes, touch and caress the baby while feeding. The new born should be kept warm by **promoting Kangaroo Mother Care** and promoting local practices to keep the room warm (6).
- d. Colostrum must not be discarded but should be fed to newborn as it contains high concentration of protective immuno-globulins and cells. **No pre-lacteal** fluid should be given to the newborn.
- e. Baby should be fed **“on cues”**. The **early feeding cues** includes; sucking movements and sucking sounds, hand to mouth movements, rapid eye movements, soft cooing or sighing sounds, lip smacking, restlessness etc. **Crying is a late cue** and may interfere with successful feeding. Babies should be breastfed at least 8-10 times in 24 hours till lactation is established (1-2 weeks) indicated by



frequent urination and stooling and adequate weight gain. Mothers should be promoted to feed the babies frequently in the early days. A sleepy baby can be easily woken up by removing blankets, removing clothes, changing loin cloth if wet, skin-to-skin contact in kangaroo position and gently massaging the back and the limbs. Periodic feeding is practiced in certain situations like in the case of a very small infant who is likely to become hypoglycemic unless fed regularly, or an infant who 'does not demand' milk in initial few days. Periodic feeding should be practiced only on medical advice. Adequacy of breastfeeding in this critical period should be monitored by clinical parameters complemented by weighing on digital weighing scale (minimum sensitivity of 5 gms) on day 1, 4, 7, 14 and 28. Maternity service should have a protocol to manage post-discharge follow ups of all newborns along-with protocols for excessive weight loss (>10% - 12.5%) and weight faltering.

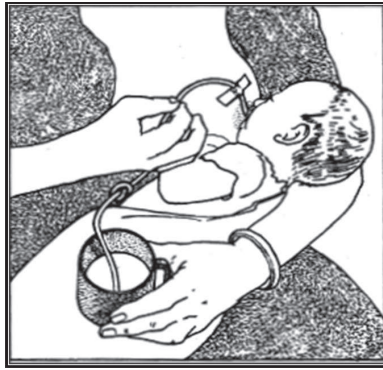
- f. Every mother, specially the primi should receive **breastfeeding support** from the doctors and the nursing staff, or community health workers (in case of non institutional birth) with regards to correct positioning, latching and treatment of problems, such as breast engorgement, nipple fissures and delayed '**coming-in**' of milk. If available dedicated skilled breastfeeding supports like Lactation Consultants (IBCLCs: International Board Certified Lactation Consultants)/Mother Support Counsellors/Peer Counsellors should be facilitated to support the mother in the antenatal, immediate postnatal period, post discharge follow ups and in NICUs.
- g. **Exclusive breastfeeding** should be practiced **from birth till end of six months (180 days)**. This means that no other food or fluids should be given to the infant below six months of age unless medically indicated. After completion of six months, with introduction of optimal complementary feeding, breastfeeding should be **continued for a minimum for 2 yrs and beyond** depending on the choice of mother and the baby. Even during the second year of life, the frequency of breastfeeding should be 4-6 times in 24 hours, including night feeds.
- h. Mothers need **skilled help and confidence building** during all health contacts and also at home through home visits by trained community worker, especially after the baby is 3 to 4 months old when a mother may begin to doubt her ability to fulfill the growing

needs and demands of the baby.

- i. The main reason given by majority of working mothers for stopping breastfeeding is their return to work following the maternity leave. Mothers who work outside should be assisted with obtaining adequate **maternity/Baby Care/breastfeeding leave** from their employers, should be encouraged to continue exclusive breastfeeding for 6 months by expressing milk for feeding the baby while they are out at work, and initiating the infant on timely complementary foods. They may be encouraged to carry the baby to a work place crèche wherever such facility exists. The concept of **“Hirkani’s Rooms”** may be considered at work places (Hirkani’s Rooms are specially allocated room at the workplace where working mothers can express milk and store in a refrigerator during their work schedule). Every such mother leaving the maternity facility should be taught manual expression of her breast milk, however for a working mother this skill would prove invaluable.
- j. Mothers who are unwell or on medication should be encouraged to continue breastfeeding unless it is medically indicated to discontinue breastfeeding.
- k. At every health visit, **the harms of artificial feeding and bottle feeding** should be explained to the mother. Inadvertent advertizing of infant milk substitute in health facility should be avoided. Artificial feeding or supplementation is to be practiced only when medically indicated.
- l. If the breastfeeding was temporarily discontinued due to an inadvertent situation, **“re-lactation”** should be tried as soon as possible (7). Such cases should be referred to a trained lactation consultant / health worker. Supplemental Suckling Technique (SST) is a technique which can be used as a strategy to initiate relactation in mothers who have developed lactation failure or Mother’s Milk Insufficiency (MMI). WHO recommends relactation through Supplemental Suckling Technique (Fig.1). The drip and drop method helps to sustain the infant’s interest of suckling at the breast (8).
- m. The possibility of **“induced lactation”** shall be explored according to the situation e.g. adoption, surrogacy. Induced lactation assumes importance for women who plan to adopt a baby. It helps to create mother - infant bonding apart from security and comfort for the

baby. The technique involves motivating the surrogate mother, having a willing and vigorously sucking infant and an adequate support group. Prolactin and oxytocin, the hormones which govern lactation, are pituitary and not ovarian. Hence, stimulation of nipple and areola and repeated suckling by the baby are important. Lact-aid as nursing trainer is also useful (9). A course of prolactin enhancing drugs such as Metoclopramide is initiated (10). Non-puerperal Lactation in surrogate mothers has been successfully demonstrated among Indian mothers (11).

Figure 1: Supplemental Suckling Technique



- n. Nursing in Public (NIP): Mothers should feel comfortable to nurse in public. The mindset of the community also needs to change in order to facilitate mother to NIP. All efforts should be taken to remove hurdles impeding breastfeeding in public places, special areas/rooms shall be identified/ constructed or established in places like Bus stands, Railway stations, Air ports etc.
- o. Adoption of latest **WHO Growth Charts** is recommended for monitoring growth (12).

2. Complementary Feeding (13)

- a. Appropriately thick homogenous complementary foods made from locally available foods should be **introduced at six completed months** to all babies **while continuing breastfeeding *ad libitum*** (14,15). This should be the standard and universal practice. During this period breastfeeding should be actively supported and the term “Weaning” should be avoided (16). Complementary feeding should

be projected as the bridge that the mother has to make between liquid to solid transition and to empower the baby to 'family pot feeding'.

- b. To address the issue of a small stomach size which can accommodate limited quantity at a time, each meal must be made **energy dense** by adding sugar/jaggery and ghee/butter/oil. To provide more calories from smaller volumes, food must be thick in consistency - thick enough to stay on the spoon without running off, when the spoon is tilted (17). (Photograph/image in Figure 2).

Figure 2: Consistency of Complementary food



- c. Foods can be **enriched by making a fermented** porridge, use of **germinated or sprouted flour** and toasting of grains before grinding (16,18).
- d. Adequate total energy intake can also be ensured by addition of one to two nutritious snacks between the three main meals. **Snacks are in addition to the meals and should not replace meals.** They should not to be confused with foods such as sweets, chips or other processed foods (18).
- e. Parents must identify the staple **homemade food comprising of cereal-pulse mixture** in the ratio 2:1, (as these are fresh, clean and cheap) and make them caloric and nutrient rich with locally available products.
- f. The research has time and again proved the disadvantages of bottle feeding. Hence **bottle feeding shall be discouraged** at all levels.
- g. Population-specific dietary guidelines should be developed for complementary feeding based on the food composition of locally available foods. A list of **appropriate, acceptable and avoidable** foods can be prepared.
- h. The food should be a **“balanced diet”** consisting of various (as diverse as possible) food groups/components in different combinations. As the babies show interest in complementary feeds,



the variety should be increased by adding new foods in the staple food one by one. Easily available, cost-effective seasonal uncooked fruits, green and other dark colored vegetables, milk and milk products, pulses/legumes, animal foods, oil/butter, sugar/jaggery may be added in the staples gradually (16, 17).

- i. Avoid giving drinks with low nutrient value, such as tea, coffee and sugary drinks.
- j. **Hygienic practices** are essential for food safety during all the involved steps viz. preparation, storage and feeding. Freshly cooked food should be consumed within one to two hours in hot climate unless refrigerated. **Hand washing** with soap and water at critical times- including before eating or preparing food and after using the toilet (17, 18).
- k. **Practice responsive feeding.** Young children should be encouraged to take feed by praising them and their foods. Self feeding should be encouraged despite spillage. Each child should be fed under supervision in a separate plate to develop an individual identity. Forced feeding, threatening and punishment interfere with development of good/proper feeding habits (17). Along with feeding mother and care givers should **provide psychosocial stimulation to the child** through ordinary age-appropriate play and communication activities to **ensure early childhood development.** TV viewing while feeding as a reward or bribe should be avoided. Serving small quantities and positive reinforcement for finishing the food should be practiced instead of serving large quantities and blaming the baby for not finishing.
- l. A skilled help and confidence building is also required for complementary feeding during all health contacts and also at home through home visits by community health workers.
- m. Consistency of foods should be appropriate to the developmental readiness of the child in munching, chewing and swallowing. **'Neophobia'** is the rule in them and any item may have to be offered several times for acceptance. Avoid foods which can pose choking hazard. Introduce lumpy or granular foods and most tastes by about 9 to 10 months. Missing this age may lead to feeding fussiness later. So do not use mixers/grinders to make food semisolid/pasty. The details of food including; texture, frequency and average amount are enumerated in Table - 1.

Table - 1: AMOUNTS OF FOODS TO OFFER (18, 19)

Age	Texture	Frequency	Avg. Amt each meal.
6-8 months	Start with thick porridge, well mashed foods	2-3 meals per day plus frequent BF	Start with 2-3 tablespoonfuls
9-11 months	Finely chopped or mashed foods, and foods that baby can pick up	3-4 meals plus BF. Depending on appetite offer 1-2 snacks	½ of a 250 ml cup/ bowl
12-23 months	Family foods, chopped or mashed if necessary	3-4 meals plus BF. Depending on appetite offer 1-2 snacks	¾ to one 250 ml cup/bowl
If baby is not breastfed, give in addition: 1-2 cups of milk per day, and 1-2 extra meals per day.			
The amounts of food included in the table are recommended when the energy density of the meals is about 0.8 to 1.0 Kcal/g. If the energy density of the meals is about 0.6 Kcal/g, recommend to increase the energy density of the meal (adding special foods) or increase the amount of food per meal. Find out what the energy content of complementary foods is in your setting and adapt the table accordingly			

3. HIV and Infant Feeding

“The following guidelines of HIV and Infant Feeding are based on recommendations given by WHO and NACO.” (Ref : 20-26) :

- a. **Counseling for infant feeding should begin in the antenatal period.** All HIV infected pregnant women should be informed about infant feeding options, viz. exclusive breast feeding or exclusive replacement feeding. Breast feeding is the preferred choice in developing countries as it maximizes the chances of survival of the infant. The health care providers and counselors should be trained to help the pregnant women in reaching the right decision and to support them in implementing breast feeding (20).
- b. **In resource-limited settings, HIV infected mothers of HIV uninfected infants** often face a difficult dilemma regarding infant feeding. Breastfeeding risks transmission of HIV to their infants, however formula feeding may not be a viable option due to high cost, lack of clean water or stigma associated with not breastfeeding. The risk of HIV transmission through breast milk is greatest in the first several months of life; however, a lower but constant risk



persists throughout the entire breastfeeding period. Recent clinical studies have established that HIV infected mothers can breastfeed with minimal risk of HIV transmission to their infants as long as the mother and the infant receive appropriate **antiretroviral prophylaxis**.

- c. **Care for the HIV-infected pregnant women** begins on the first contact with health services during the ante natal period. Establishing a relationship or a rapport with the HIV infected pregnant woman is fundamental in providing a continuum of care involving prevention, care, support, and treatment for the mother and child. All HIV infected pregnant women should have PPTCT interventions provided early in pregnancy as far as possible (21).
- d. **Current WHO 2013 guidelines recommended two options:**
 - A) **Providing lifelong ART** (one simplified triple regimen) to all pregnant and breastfeeding women regardless of CD4 count or clinical stage. B) **Providing ART (ARV drugs)** for pregnant and breastfeeding women during the period of risk of mother-to-child transmission and then continuing lifelong ART for those women meeting eligibility criteria for their own health (20,22).
- e. **Government of India** is committed to work towards achievement of the global target of **“elimination of new HIV infections among children”** by 2015. Based on the new guidelines from WHO (June 2013), department of AIDS Control (NACO) has decided to **provide life-long ART (triple drug regimen) for all pregnant and breast feeding women living with HIV**, in which they receive treatment regardless of CD4 count or WHO clinical stage, both for their own health and to prevent vertical HIV transmission from mother-to-child. This would also help in maximizing coverage, for keeping them alive and for their own health, avoiding stopping and starting drugs with repeat pregnancies, provide early protection against mother-to-child transmission in future pregnancies and avoiding drug resistance. These recommendations have the potential to reduce the risk of mother-to-child-transmission to less than 5 per cent in breastfeeding populations. These guidelines have been implemented across the country from 1st January 2014 (21).
- f. **Providing an optimized, fixed-dose combination once daily** first-line ARV regimen of Tenofovir, Lamivudine (or Emtricitabine)

and Efavirenz to all pregnant and breastfeeding women provides important programmatic and clinical benefits (22,23,24). Where access to CD4 testing is limited, WHO prefers that all pregnant and breastfeeding HIV-infected women, regardless of CD4 cell count, should continue antiretroviral treatment for life (sometimes called “**Option B+**”). In other countries, for women who are not eligible for treatment, consideration can be given to stopping the antiretroviral regimen after the period of mother-to-child transmission risk has ceased (sometimes called “**Option B**”). Thus, for breastfeeding women with a CD4 cell count >500 cells/microL, antiretrovirals should be continued until at least one week after complete cessation of breastfeeding (Option B) or lifelong (Option B+), depending on the national program.

- g. **Mothers known to be infected with HIV** (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding as long as possible. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast-milk can be provided. Initiate maternal ART and give NVP for 6 weeks.
- h. **Infants of mothers who are receiving ART** and are breastfeeding should receive six weeks of infant prophylaxis with daily NVP. If infants are receiving replacement feeding, they should be given four to six weeks of infant prophylaxis with daily NVP (or twice-daily AZT). Infant prophylaxis should begin at birth or when HIV exposure is recognized postpartum (20, 21).
- i. **Mother diagnosed with HIV during labor** or immediately postpartum and **plans to breastfeed**, initiate maternal ART and give to the infant extended NVP prophylaxis to 12 weeks.
- j. **Mother diagnosed with HIV during labor** or immediately postpartum and plans **Exclusive Replacement feeding (ERF)**. Refer mother for HIV care and evaluation for treatment. Give infant NVP prophylaxis to 6 weeks.
- k. **Infant identified as HIV exposed after birth** (through infant (at 6 weeks or after) or maternal HIV antibody testing) **and is breastfeeding**. Initiate maternal ART and give to the infant NVP prophylaxis. Perform infant DNA/PCR test if child is 6 weeks old



or older, immediately initiate 6 weeks or longer of NVP– strongly consider extending this to 12 weeks.

- i. **Infant identified as HIV exposed after birth** (through infant or maternal HIV antibody testing) and **is not breastfeeding**. Refer mother to ART Centre after CD4 tests and baseline test and treatment. No NVP (No drugs) is to be started. Do HIV DNA/PCR test in accordance with national recommendations on early infant diagnosis; no infant ARV prophylaxis; initiate treatment if the infant is infected (25).
- m. **Mother receiving ART but interrupts ART regimen while breastfeeding** (such as toxicity, stock-outs or refusal to continue). Determine an alternative ART regimen or solution; counsel regarding continuing ART without interruption. NVP is given until 6 weeks after maternal ART is restarted or until 1 week after breastfeeding has ended. The recommended dose of Navirapine is shown in Table - 2.
- n. **Exclusive breastfeeding** is the preferred feeding option for HIV-exposed infants <6 months of age. However, if in some women breastfeeding may not be possible – for example in situations of maternal death and severe maternal illness in which case **Exclusive Replacement Feeding** should be done only when AFASS criteria is fulfilled: A – Affordable F – Feasible A – Acceptable S – Sustainable and S – Safe. Exclusive breastfeeding should be done for at least 6 months, after which complementary feeding should be introduced gradually, irrespective of whether the infant is diagnosed HIV negative or positive by EID (Early Infant diagnosis).
- o. For breastfeeding **infants diagnosed HIV negative**, breastfeeding should be continued until 12 months of age ensuring the mother is on ART as soon as possible.
- p. The Early Infant diagnosis (EID) is repeated for the 3rd time (when previous 2 EIDs have been negative) after **6 weeks of stopping breast feeds**, repeat EID i.e., Rapid test followed by Dried Blood Spots (if Rapid Test turns positive) send DBS test. If DBS is positive, do a Whole Blood Sample (WBS) test. If WBS test is positive, Pediatric ART should be initiated. However, confirmation test for HIV has to be done at 18 months using 3 Rapid Tests for all babies irrespective of the earlier EID status or the fact that Pediatric ART has already been initiated.
- q. For breastfeeding infants who have been diagnosed HIV positive,

pediatric ART should be started and breastfeeding to be continued ideally until the baby is 2 years old (25).

- r. Breastfeeding should stop once a **nutritionally adequate and safe diet** without breast milk can be provided. **Breast-feeding should NOT be stopped ABRUPTLY.** Gradually wean from breast milk over a one month period.

Table 2: DOSES OF NEVIRAPINE

Infant age	Nevirapine
Birth to 6 weeks (Birth weight 2000-2499 g)	10 mg once daily
Birth to 6 weeks (Birth weight \geq 2500 g)	15 mg once daily
>6 weeks to 6 months	20 mg once daily
>6 months to 9 months	30 mg once daily
>9 months to end of breastfeeding	40 mg once daily

Alternatives to breastfeeding include:

For infants less than 6 months of age:

- i. Expressed, heat-treated breast milk
- ii. Unmodified animal milk
- iii. Commercial infant formula milk.

(The choice / selection shall be based on AFASS criteria)

For children over 6 months of age:

- iv. All children can be given complementary foods from six months of age (as discussed in the section on complimentary feeding).

Other options for all ages:

- v. Breastfeeding by another woman who is HIV negative (**wet-nursing**)
- vi. Human milk from **breast milk banks.**

Replacement Feeding (RF) is the process of feeding a child who is not receiving any breast milk, with a diet that provides all the nutrients until the child is fully fed on family foods. The replacement feeding option should be selected, only if all of the **AFASS criteria** are completely fulfilled. Cup feeding should be the method of choice if replacement feeding needs to be done and bottles should be totally avoided. If any of the AFASS criteria is not met, the mother should practice exclusive breastfeeding till 6 months along with early treatment of breast and nipple problems.



Mixed feeding must be avoided (except the short transition period of around a month when breastfeeding is being gradually stopped) as it causes a two fold increase in the risk of postnatal HIV transmission. Local breast conditions like nipple fissures can increase the risk of HIV transmission and hence should promptly be treated.

Mothers known to be HIV infected may consider expressing and heat-treating breast milk as *an interim feeding strategy* in special circumstances such as:

- a) When the infant is born with low birth weight or is otherwise ill in the neonatal period and unable to breastfeed; **or**
- b) When the mother is unwell and temporarily unable to breastfeed or has a temporary breast health problem such as mastitis; **or** If antiretroviral drugs are temporarily not available.

4. Concept and need of Human Milk Banks in India

- a. Human Milk Banks should be promoted considering the large number of babies needing PDHM (pasteurized donor human milk) when MoM (Mother's own Milk) is not available. In 1980 the World Health Organization and UNICEF jointly declared: "Where it is not possible for the biological mother to breastfeed, the first alternative, if available, should be the use of human milk from other sources. Human milk banks should be made available in appropriate situations" (26).
- b. Cost effectiveness of using banked human milk in neonatal intensive care units has been documented in Western countries, largely due to reduction in rates of NEC (Necrotizing Enterocolitis) (27,28), reduction in severe infections (29,30,31) and decreased length of hospital stay for babies fed expressed human breast milk (32). Given the high incidence of sepsis and a large burden of premature births, this intervention has a potential to result in substantial saving for the nation in terms of finances and human capital.
- c. Presence of human milk bank is also a factor promoting breastfeeding.
 - i. Use of PDHM in NICU is associated with increased breastfeeding rate at discharge from the hospital for VLBW infants (33).
 - ii. The novel approach of promoting human milk banks through mode of collecting breast milk donations in form of camps is a

strong means of promoting breastfeeding in the society.

- d. It is recommended that there should be a human milk bank in each SNCU/NICU initially preferably in government set-up and subsequently in private and corporate sectors.

5. Feeding in other specific situations

- a. **Feeding during sickness** is important for recovery and for prevention of under nutrition. Even sick babies mostly continue to breastfeed and the infant can be encouraged to eat small quantities of nutrient rich food but more frequently and by offering foods that the child likes to eat. After the illness the nutrient intake of child can be easily increased by increasing one or two meals in the daily diet for a period of about a month; by offering nutritious snacks between meals; by giving extra amount at each meal; and by continuing breastfeeding.

b. Infant feeding in maternal illnesses:

- i. Painful and/or infective breast conditions like breast abscess and mastitis and psychiatric illnesses which pose a danger to the child's life e.g. postpartum psychosis, schizophrenia may need a temporary cessation of breastfeeding. Treatment of primary condition should be done and breastfeeding started as soon as possible.
- ii. Chronic infections like tuberculosis, leprosy, or medical conditions like hypothyroidism need treatment of the primary condition and don't warrant discontinuation of breastfeeding.
- iii. Breastfeeding is contraindicated when the mother is receiving certain drugs like anti-neoplastic agents, immuno-suppressants, antithyroid drugs like thiouracil, amphetamines, gold salts, etc. Breastfeeding may be avoided or continued with caution when the mother is receiving following drugs - atropine, reserpine, psychotropic drugs. Other drugs like antibiotics, anesthetics, antiepileptics, antihistamines, digoxin, diuretics, prednisone, propranolol etc. are considered safe for breastfeeding (34).

c. Infant feeding in various conditions related to the infant:

- i) Breastfeeding on demand should be promoted in normal active babies. However, in difficult situations like very LBW, sick, or depressed babies, alternative methods of feeding can be used



based on neuro-developmental status. These include feeding expressed breastmilk through intra-gastric tube or with the use of cup and spoon. For very sick babies, expert guidance should be sought. If the baby is transferred to NBSU/SNCU/NICU, mothers should be supported to start breastmilk expression within hours of delivery, continue it at least 3 hourly during the day time and at least once at night. Arrangements should be made to transfer this milk to the baby.

- ii) Ensure early transfer of mothers with the baby in NBSU/SNCU/NICU and that NBSU/SNCU/NICU has arrangement to accommodate the mothers in the immediate vicinity and that mothers are permitted to visit and hold and touch the baby at will if the baby's condition permits.
- iii) Ensure that majority of babies are on exclusive breastfeeding or on breastfeeding plus expressed breastmilk at discharge from the NBSU/SNCU/NICU.
- iv) **Gastro-Esophageal Reflux Disease (GERD):** Mild GERD is often treated conservatively through thickening the complementary foods, frequent small feeds and upright positioning for 30 minutes after feeds.
- v) **Primary Lactose Intolerance** is congenital and may require long term lactose restriction. **Secondary Lactose Intolerance** is usually transient and resolves after the underlying GIT condition has remitted. Most of the cases of diarrhea do not require stoppage of breastfeeding.
- vi) Various **Inborn Errors of Metabolism** warrant restriction of specific offending agent and certain dietary modifications e.g. in Galactosemia, dietary lactose and galactose should be avoided. This is probably the only absolute contraindication to breastfeeding.
- vii) **During emergencies**, priority health and nutrition support should be arranged for pregnant and lactating mothers. Donated or subsidized supplies of breastmilk substitutes (e.g. infant formula) should be avoided, must never be included in a general ration distribution, and must be distributed, if at all, only according to well defined strict criteria. Donations of bottles and teats should be refused, and their use actively avoided.

6. Micronutrient in Infant Feeding

- a. Micronutrients enhance nutritional value of food and have profound impact on a child's development.
- b. Breastmilk has usually adequate amount of Iron, Calcium, Phosphorus, Vitamin A etc for a normal newborn. Preterm infants who are breastfed should receive 2 mg of supplemental iron per kg of body weight each day by one month of age (35). Preterm and low birth weight may also need calcium and multivitamin supplements.
- c. Breastfed infants can maintain normal vitamin D status in the early post-natal period only when their mother's vitamin D status is normal and /or the infants are exposed to adequate amount of sunlight.
- d. Corroborative evidences of high prevalence of vitamin D deficiency in Indian infants suggest that they should be given routine vitamin D supplementation of 400 IU daily, especially in those with higher risk of getting less of vitamin D. Even those on formula feeds need supplementation unless they consume more than 1000 ml of formula daily (36,37). VLBW infants should be given vitamin D supplements at a dose ranging from 400- 1000 IU per day until six months of age (38).
- e. Items that supply micronutrients should be encouraged like GYOR (green, yellow, orange & red) vegetables and fruits, Use of food fortification like Iron-fortified foods, iodized salt, vitamin A enriched food etc. are to be encouraged.

7. Junk Food and Infant Feeding

- a. Consumers are often bewildered by nutritive & health claims, while children are highly influenced by advertisements enticing them to buy a product which may be unhealthy or in fact detrimental (39).
- b. The parents should understand that though the companies are promoting many foods as "**Magic food**" in reality such products don't exist.
- c. **Avoid Junk and Commercial food** which are high in fat, sugar, salt & pesticides/additives (HFSSP). Avoid giving ready-made, processed commercial food from the market, e.g. tinned foods/juices, colas & carbonated drinks, cold-drinks, chocolates, crisps, health drinks,



bakery products etc.

- d. Junk foods are one of the important reasons for the increasing incidences of childhood obesity. There is need to restrict consumption of junk food especially in and around educational institutions and remote areas of the country.
- e. The various products with exaggerated claims **shall not be freely available on the counter**. The availability of such products shall be restricted or may be **sold on prescription** of a registered medical practitioner.
- f. The provisions of The Food Safety & Standards Act 2006 shall be implemented and monitored regularly (40).

8. Maternal Nutrition

- a. In India, 22% babies born each year have LBW, which has been linked to maternal under-nutrition and anemia among other causes. The mother's condition before pregnancy is a key determinant of its outcome; half of adolescents (boys and girls) have below normal body mass index (BMI) and almost 56% of adolescent girls aged 15–19 years have anemia.
- b. Optimal nutrition of adolescent girls, Pre-Pregnant women and pregnant mothers is critical to intrauterine growth, fetal well-being and to prevent malnutrition in the postnatal period (41).
- c. There is a growing evidence that maternal nutritional status can alter the epigenetic state (stable alterations of gene expressions through DNA methylation and histone modifications) of the fetal genome. This may provide a molecular mechanism for the impact of maternal nutrition on both fetal programming and genomic imprinting. Just as the damaging effects of malnutrition, pass from one generation to the next, so can benefits of good nutrition (42).
- d. Maternal calcium, folic acid and iron supplementation is important. There is ample universal evidence that calcium supplementation in pregnancy reduces incidence of pre-eclampsia and other hypertensive disorders in pregnancy.
- e. The maternal nutrition should also be balanced, fresh and preferably home-made and there should not be any unscientific restrictions.

B. Operational Guidelines

1. Recommendations for Governmental and International Agencies

- a. Global legislation, binding to all states and private organizations including labor benefits, **6 (six) months maternity and appropriate paternity leave** is strongly recommended. Maternity leave, day care facilities and paid breastfeeding breaks should be available to all employed women in all sectors including those engaged in atypical forms of dependent work e.g. part time, domestic and intermittent employment.
- b. **Breastfeeding is a human right both for the mother as well as baby.** With due weightage and respect to National Family Planning Policies and Program, the benefits should be given to mother and the child (even after 2 issues) born out of unplanned pregnancy (Family planning method failure) or as a result of accidental death of previous child.
- c. Scientific and unbiased IYCF practices must be promoted through **regular advertisements** in state, public or private owned audiovisual and print media. Public should be made aware that **artificial, junk or packaged food can be injurious to the health** of the children.
- d. Necessary and adequate arrangements should be made for **propaganda and implementation** of the provisions of Infant Milk Substitute (**IMS**) Act which prevents advertising or promoting infant milk substitutes. In addition, further strengthening of the existing Act must be tried.
- e. Adopt a National policy to avoid conflict of interests in the areas of child health and nutrition. Popularization of “**unscientific health claims**” by commercial ads through media needs to be restricted. UN agencies shall help in promoting the home made / available food (especially through various media) with the help of their brand ambassadors / endorsers.
- f. There should be **board, commission or committee to monitor, evaluate & censor the product** before it is released in the market. Such board or committees shall have a sensitized pediatrician



and/or other equivalent health care expert/nutrition expert. A pediatrician shall also be involved in the commission/committee/board entrusted with drafting of any code, bill, laws, rules/regulations related to food, nutrition, drinks, food products, etc.

- g. Government should explore the possibility of appointing or making **Lactation counselor** available at least at Block level.
- h. Government along with International agencies should formulate **National policy on Fortification** of food with micronutrients.
- i. The experts, academicians and government shall formulate/develop guidelines for **management of Severe Acute Malnutrition** (including effective home based care and treatment) in children.
- j. Human Milk Banks shall be promoted, established and maintained at least in District/Civil hospitals and Medical colleges.

2. Role of NGOs

- a. Various programs or community projects should be initiated to provide home care and counseling on IYCF through formation of **mother support groups** especially by women's organizations.
- b. The voluntary organizations should understand and advocate important recommendations at all levels. Various **like-minded organizations** should work preferably on the same platform and co-ordinate with each-other in promoting the IYCF practices.

3. Recommendations for Media

The Media can have a vital role to play in strengthening the knowledge chain, serving as a link between the stakeholders and the community as **"community is exposed to images, articles and ideas in innumerable ways"** from TV, newspaper headlines, magazine covers, movies, websites, video games and road side signboards. Media has a great power but it is high time that it recognizes its responsibility towards child nutrition by:

- a. Media has to take concrete steps to **avoid directly or indirectly glamorizing/promoting** bottle feeding, artificial, commercial and ready to use food. Instead, the risks involved in artificial feeding and other suboptimal feeding practices should be advertised **prominently in bold prints**.

- b. **Media support** is even more important on certain occasions, celebrations, and social mobilization activities such as World Breast Feeding Week and Nutrition Weeks.
- c. The companies & media should have self-regulatory pledge for responsible advertising/marketing. They should help in promoting healthier dietary choices and a more active life style for Indian children.
- d. **Sportsman, Celebrities should not promote** various products unless evidence based scientifically sound & authentic information is publicized.

4. Recommendations for Training

- a. It is recommended that all the community health workers, PPTCT counselors, and other personnel caring for children including doctors should undergo three days skill training on IYCF (including IMS Act). In situations where three day training is not feasible, some impact can be made with short duration sensitization programs (half day/one day).
- b. IYCF should also be **included in the curriculum of** undergraduate and postgraduate medical education, nursing education, home science, child nutrition courses etc.
- c. Anganwadi workers, ASHA, Dai`s and other grass root level workers should be empowered by basic, scientific information related to IYCF.
- d. State, National and International Level workshops on IYCN should be organized at regular intervals for capacity building of IYCN Resource Personnel. A multi-sectorial effort should be initiated to create this skilled human resource.
- e. In addition to above measures dedicated skilled breastfeeding (IYCN) support is critical to achieve IYCN goals. Hence there is a need to launch an ambitious program to create a spectrum of such resources [Lactation Consultants (IBCLC), IYCN Counsellors and Peer Counsellors).
- f. Training Programs should ensure that the trainers start extending help to beneficiaries in terms of improving initiation and exclusive breastfeeding rates and timely help for breastfeeding problems.



Baby Friendly Concepts:

Baby Friendly Hospitals Initiatives (BFHI) is recommended to be spread to all especially medical college hospitals departments. The revised and expanded version of BFHI has been implemented by UNICEF and WHO in 2009 (43). BFHI was implemented partially in some states of India in 1992 but over the years it has not been reinforced or reevaluated. Strengthening of this initiative in the community would lead to better child survival.

These guidelines do not provide all of the answers but through the applications of these guidelines in day to day practices, child nutrition in the Indian subcontinent will improve remarkably.

Key Messages

1. Initiation of breastfeeding as early as possible after birth, preferably within one hour.
2. Exclusive breastfeeding in the first six months of life and no other foods or fluids (no water, juices, tea, pre-lacteal feeds), with the exception of drops or syrups consisting of micronutrient supplements or medicines in compromised/diseased babies.
3. Appropriate and adequate complementary feeding after completion of six months of age while continuing breastfeeding. Complementary foods should not be confused with supplementary foods.
4. Hand washing with soap and water: Hand washing with soap and water at critical times – including before eating or preparing food and after using the toilet.
5. Avoid junk food with high caloric content, sugar and salts and with exaggerated health claims. Home food should be preferred over artificial, commercial, tinned or packaged food.
6. Promote and establish Human Milk Banks.
7. Full immunization, Vitamin-A, Vitamin-D and Iron supplementation with deworming.
8. Appropriate feeding for children during and after illness.
9. Effective home based care and treatment of children suffering from severe acute malnutrition.
10. Adequate nutrition and anemia control for adolescent girls, pregnant and lactating mothers.
11. Effective implementation and monitoring of IMS Act and other laws related to child nutrition.



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Human Milk Banking Guidelines: Indian Perspective 2015

Justification:

Millennium Development Goal-4 aims to reduce under-five child mortality by two-thirds by 2015. In order to accelerate the progress on child survival there is heightened global interest in increasing the rates of optimal infant and young child feeding practices, especially the human milk for the first six months. The under-five mortality rate (U5MR) for India was estimated at 59 for the year of 2010. If India is to reach the MDG Goal of U5MR of 42 by 2015, the average annual rate of reduction over the next three years must be far higher.

Infant Mortality Rate (IMR) in India has registered a decline from 58 in 2005 to 44 in 2011. WHO estimates that 53 per cent of acute pneumonia and 55 per cent of diarrhoea deaths are attributable to poor feeding practices during the first six months of life. WHO and UNICEF, made a joint statement in 1980: "Where it is not possible for the biological mother to breast feed, the first alternative, if available, should be the use of human milk from other sources. Human milk banks should be made available in appropriate situations." Hence Human Milk Banks and its quality assurance in the country need to be maintained uniformly so that best outcomes are possible.

Objectives:

The purpose of this document is to ensure quality of donated breast milk as a safe end product. It is expected that this document would help the existing and upcoming Human Milk Banks to ensure the quality of donated human milk.

Key words:

Human milk banking, malnutrition, child survival, U5MR, MDG



Human Milk Banking Guidelines: Indian Perspective 2015

Abbreviations:

PDHM (Pasteurized Donor Human Milk), HMB (Human Milk Bank)

Introduction:

Breastfeeding is the best method of infant feeding because human milk continues to be the only milk which is uniquely suited to the human infant. All mothers should be encouraged to breast feed their own infants. When a mother, for some reason, is unable to feed her infant directly, her breastmilk should be expressed and fed to her infant. If mother's own milk is unavailable or insufficient, the next best option is to use PDHM. India faces its own unique challenges, having the highest number of low birth weight babies and significant mortality and morbidities in VLBW population. In our country, the burden of low birth weight babies in various hospitals is about 20% with significant mortality and morbidities (1), (2). Feeding these babies with breastmilk can significantly reduce the risk of infections. Hence the Government, health experts and the civil society must join hands to propagate the concept of human milk banking for the sake of thousands of low birth weight and preterm babies.

Though wet nursing had been in practice since mythological ages, modern human milk banking is in its infancy in India. Lack of awareness, leadership deficit, infrastructural and maintenance cost, fewer NICU setups etc are few reasons for the same. The first milk bank in Asia under the name of 'Sneha', founded by Dr. Armeda Fernandez, was started in Dharavi, Mumbai on November 27, 1989. Currently, the number of human milk banks has grown to nearly 14 all over India but the growth of human milk banks have been very slow as compared to the growth of neonatal intensive care units. These guidelines don't intend to present detailed scientific literature but are an attempt to backup the execution of establishment and operation of human milk banking with scientific methods.

Location of HMB:

Human milk banks are primarily focused to provide donor milk to high risk newborns admitted in the neonatal unit. Therefore, a location

in close proximity or even inside the boundaries of neonatal unit is desirable. Presence of human milk banks in the NICUs is associated with elevated rates of exclusive breastfeeding rates in VLBW babies (3). Post natal wards or Well baby Clinics of the large hospitals are most suited for the purpose as the number of donors is likely to be found in large numbers where medical and nursing staffs can encourage them to donate milk.

The Recipients:

PDHM can be prescribed on priority for:

- Preterm babies and sick babies
- Babies of mothers with postpartum illnesses
- Babies whose mothers have lactation failure, till their milk output improves in extremely preterm infants given exclusive diets of preterm formula versus human milk, there was a significantly greater duration of parenteral nutrition and higher rate of surgical NEC in infants receiving preterm formula (4). It is possible to administer trophic feeds/gut priming early enteral feeds exclusively with human milk in VLBW infants with banked human milk (5).

If PDHM supplies are sufficient donor milk may be supplied for:

- Absent or insufficient lactation: Mothers with multiple births, who can't secrete adequate breastmilk for their neonates initially.
- For babies of non lactating mothers, who adopt neonates and if induced lactation is not possible.
- Abandoned neonate and sick neonate.
- Temporary interruption of breastfeeding.
- Infant at health risk from breastmilk of the biological mother.
- Babies whose mother died in the immediate postpartum period.

Infrastructure:

There are no standard recommendations or specific guidelines mentioned regarding the space requirements for creation of human milk banks. The minimum requirement is a partitioned room of 250 square feet which can comfortably lodge at least the equipment required for milk banking, a work area for the technician as well as some storage



space for records, administration and area for counselling donors etc. Privacy is of paramount importance for area of breastmilk expression. Provision of music/television and a crèche for her baby helps in reducing stress of donors. Teaching videos of Kangaroo Mother Care (KMC) and expression of breastmilk and advantages of breastmilk feeding can be shown under supervision of milk bank staff.

Equipments:

Pasteurizer/Shaker-water bath: It is essential to have a device to carry out heat treatment of donor milk at the recommended temperature of 62.5 degrees Celsius for a period of 30 minutes (Pretoria Holder pasteurization method) prior to its use. A well accepted alternative is the use of a shaker water bath with a micro-processor controlled temperature regulator, an electronic timer device and a shaker speed controller. This shaker water bath should be double walled and made of steel. Its size varies according to the need of the milk bank, with the tray capacity varying from 9 to 24 containers of 200 to 400 ml capacity. Use of other safer methods of pasteurization with better preservation of nutrients and other properties, like flash heat treatment, HTST (High Temperature Short Time: 72.C for 16 seconds) and UV irradiation are still not being used in human milk banks routinely (6,7).

Deep Freezer: A deep freezer to store the milk at -20°C is essential in the milk bank. It is desirable to order a deep freezer with a digital display of the temperature inside it with an alarm setting. It is desirable to have 2 deep freezers for processed milk. First for storage of the milk till the post pasteurization milk culture reports are available. This freezer should be locked all times with access only to the technician, so that no milk is accidentally used till the culture reports are available. The second deep freezer is used for storage of the pasteurized milk once the culture reports are negative and the milk is considered safe for disbursement.

Refrigerators: They are required to store the milk till the whole day's collection is over and the milk is ready to be mixed and pooled for further processing. It is also required for thawing the milk before being dispatched. Preferably two different units should be used for these purposes. If not possible then, strictly earmarked areas should be kept in one unit for each purpose.

Hot Air Oven/Autoclave: A hot air oven/autoclave in the milk bank or centralized sterile service department is essential for sterilizing the

containers used for collection from donors, containers for pasteurization and the test tubes needed for sending milk culture samples to the microbiology laboratory.

Breastmilk pumps: For milk banking, hospital grade electric pumps are preferred as they result in better volumes of expressed milks and are relatively painless and comfortable to use. There is no major difference in the types of electrical breast pumps (8). Manually operated breastmilk pumps designed to operate more physiologically by simulating the infant's compressive action on the areola during breastfeeding can be used with lower cost implications (9). They can be reused with chemical disinfection/sterilization. Breast pumps can be a source of infection (10). They should be cleaned properly (11). Pump and its parts should be sterilized/disinfected as per manufacturer's instructions.

Containers: For collection and storing the milk, single use hard plastic containers of polycarbonates, pyrex or propylene are used across the world, however in Indian experiences, cylindrical, wide mouthed stainless steel containers of about 200 ml capacity with tight fitting/screwed caps are equally effective. They are easily available, durable, easy to clean and autoclave. There is no significant decrease in nutrient composition on storage; however, cellular components are reduced. Polythene milk bags are not suitable as they are fragile, associated with loss of lipids and vitamins and there is a risk of contamination, although some studies have challenged the loss of lipids (12).

Generator/Uninterrupted Power Supply: Every milk bank should have a dedicated centralized source of uninterrupted power supply backup to run the deep freezers and refrigerators in case of electricity failure.

Milk analyzer: It is desirable to have macronutrient analysis of breastmilk to estimate the calorie, protein and fat of a milk sample, using infra-red spectroscopy technology, in teaching hospitals as a step towards lacto engineering.

Administrative Staff:

Human milk banks should have a panel of consultants to guide overall development and functioning. It can include representatives from the areas of pediatrics/neonatology, lactation, microbiology, nutrition, public health, and food technology. It should consist of a Director (for planning, implementing and evaluating the services), Milk bank officer



(usually a doctor, for day to day running of the bank and trainings), Lactation management nurses (for counselling mothers and assisting expression of breastmilk), Milk bank technician (for pasteurization of breastmilk and microbiological surveillance), Milk bank attendant (for collecting, sterilization of the containers and maintaining hygiene), Receptionist (for record keeping and public relations) and a Microbiologist (for microbiology testing and infection control policies).

Donor Population:

The donor population is formed by healthy lactating mothers with healthy babies, who are voluntarily willing to give their extra breastmilk for other babies without compromising the nutritional needs of their own baby (13). The donors can include mothers attending well baby clinics, mothers whose babies are in NICU, mothers who have lost their babies but are willing to donate their milk, or lactating working staff in the hospital and motivated mothers from the community. Donors are not paid for their donations.

Try to reach maximum donor population using variety of avenues. Spreading awareness about possibility of breastmilk donation in society by various means including mass communication can help motivating donors. NGOs, social clubs and college students can play a good role in it.

Collection of Breastmilk:

After proper counselling; checking suitability for donation; getting written informed consent; history taking; physical examination and sampling for lab tests the donor mother is sent to designated breastmilk collection area in the milk bank or in the milk collection center/post. There breastmilk is collected by trained staff with hygienic precautions, after method of breastmilk expression is chosen by the counselled donor. Although home collection of the breastmilk is being practiced in some countries abroad but the experts felt that due of the risk of contamination and difficulty in tracking, it is better avoided it at present in our country, however, milk collection camps can be practiced under proper supervision.

Washing the breast with simple water before expression is as good as washing with disinfectant (14). There is no rationale in discarding the first few ml. of foremilk to reduce the infection rate. *Drip milk* i.e.

the milk that drips from the non-feeding breast in 20% of lactating mothers, collected with the help of breastmilk shells has been found to be nutritionally inferior with lower fat content (15) and is not recommended for banking.

The breastmilk may be expressed by manual method (hand expression) or with the help of breast pumps. Manual expression is a low cost and effective means of expression and associated with the least risk of contamination. Simultaneous breast expression in breastfeeding women is more efficacious than sequential breast expression (16). Guidelines for manual expression and use of breast pumps are given in the full version of this guidelines document. Donation should be collected in properly labelled sterile container. It should be transported to HMB under cold storage condition.

Processing:

All batches of collected raw breastmilk should be refrigerated immediately in pre-process milk freezer/refrigerator till the serological report comes negative. Fresh raw milk should not be added to the frozen milk since this can result in defreezing with hydrolysis of triglycerides (17). While mixing fresh raw breastmilk to frozen raw breastmilk previously collected from same donor it should be chilled before adding to frozen milk (18). But for sick or preterm babies it is advisable to use a new container for each pumping.

Microbiological screening of donated milk is done before (if there is no cost constraint) and as soon as possible after pasteurization. Pre-pasteurization microbiology can result in wastage of milk to the tune of about 30% in some cases (19). A bacterial count of 10^5 or more in raw breastmilk can be considered as an indicator of the milk's poor quality. Based on this and on the theoretical concern that heavily contaminated milk with specific bacteria (e.g. *S.aureus*, *E.coli*) may contain enterotoxins and thermostable enzymes even after pasteurization, expert panel selected 10^5 CFU/ml for total bacterial count, 10^4 CFU/ml for Enterobacteriaceae and *S. aureus* as threshold values which are in consonance with milk banks operating in other parts of the world (20,13). Such approach to minimize wastage of donated milk is difficult to implement in our country.

No growth is acceptable in post-pasteurization microbiology cultures. Whole pasteurized batch of culture positive container of processed milk should be discarded.



Storage:

Pasteurized milk awaiting culture report should be kept in dedicated freezer/freezer area taking precaution not to disburse it till the culture is negative. Storage should be done in the same container which is used for pasteurization. It is advisable not to transfer processed milk in other containers as it has risk of contamination. Culture negative processed milk should be kept at -20 degree centigrade in tightly sealed container with clear mention of expiry date and other relevant data on the label. It can be preserved for 3 to 6 months. Random cultures of preserved milk before disbursal can aid quality assurance.

Disbursal:

PDHM should be disbursed at physician's requisition from NICU after informed consent from recipient's parents. Preterm baby should preferably get PDHM from preterm donors. It should be done on First In First Out basis from the storage. Transport of PDHM should be done under cold storage in the same pasteurized container till its use and at earliest.

Frozen PDHM should be thawed by either defrosting the milk rapidly in a water bath at a temperature not exceeding 37°C, or under running lukewarm water taking care that the cap of the container does not come in contact with the water as it is likely to get contaminated (21). It should never be thawed in a microwave as this results in reduction in the IgA content of the milk and there is a risk of burns if the milk is used too soon (18). Milk should not be refrozen after being thawed as this increases the hydrolysis of the triglycerides in the milk. While bringing to room temperature, it should be gently agitated to make a homogenous mixture before use and should be used preferably within 3 hours to prevent contamination.

Labeling and Record Keeping:

Human Milk Banks should have an operational objective of ensuring full traceability from individual donation to recipient and maintaining a record of all storage and processing conditions. Confidentiality should be preserved by the milk bank about its records and data. Proper labelling at all levels is mandatory, from sterile container for collection of donation, pooling vessel, pasteurization container to storage containers. Labels should be water resistant and read clearly names

and ID of donors and ID and dates of pasteurization batch numbers and its expiry date. Record keeping at all levels should be meticulous for Donor Record File containing consent form, donor's & her child's data and screening reports, pasteurization batch files; and for PDHM Disbursal Record File containing relevant data including recipient consent form. Though rarely required, complications can be prevented with appropriate labeling and record keeping.

Economic Implications:

There has been a definite cost effectiveness of using banked human milk in neonatal intensive care units observed in western countries largely by reduction in the rate of NEC (22). In a country like ours, the cost of running a milk bank with potential cost saving due to reduction in NEC and sepsis rate and ultimately duration of hospital stay have not been adequately evaluated, but given the high incidence of sepsis and a large burden of premature births, this intervention is likely to result in substantial saving for the nation.

Conclusion:

It is clear that artificial formula will never provide the broad range of benefits of human milk. Given the high rate of preterm births in the country and level of malnutrition that ensues in the postnatal growth in such babies after birth, there is an urgent need for establishing milk banks across the country especially in the large NICUs of all hospitals. This document aims at providing expert opinion in the country regarding the feasibility and operational guidelines for establishing the milk banks.

Note: *This document is the abridged version of detailed guidelines. The detailed guidelines are available with IAP IYCF Chapter and can be obtained from the website www.iycfchapteriap.org*

This guideline has been published in Indian Pediatrics Journal. It can be cited as "Bharadva, et al. Human milk banking guidelines. Indian Pediatr. 2014;51:469-474."



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