HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Leadership		
Document:	Multidisciplinary Policy and Procedure		
Title:	Breast Milk Substitutes In Hospital		
Applies To:	All Healthcare Workers		
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1. PURPOSE:

1.1 Promote breastfeeding and the optimal use of breastmilk substitutes.
1.2 Assert the safety of breastmilk substitutes provided for newborns and infants in hospitals, as well as methods of preparing these nutrition supplements and their quality.
1.3 Restrict infants' milk formula prescription to medical and social indications or after providing counselling on breastfeeding.
1.4 Describe the method of securing, receiving, storing and prescribing breast-milk substitutes for newborns, infants and young children up to 24 months of age, depending on their health status at the hospital.

2. DEFINITONS:

2.1 **Requesting wet nurse -** The parents or a parent requesting another mother (who did not bear or give birth to the infant) to breastfeed their infant.
2.2 **Breastfeeding dyad**: The practice of breastfeeding directly or through breast milk expression, either by the mother who give birth or a wet nurse who does not give birth to the infant
2.3 **Package**: Any form of product packaging for breast milk substitutes.
2.4 **Breastmilk Substitutes Code and its Executive Regulation:** Regulation issued by the Honorable Council of Ministers' Resolution No. 260. The objective of which is to provide safe and appropriate nutrition for infants in order to protect and promote breastfeeding and to ensure the correct use of breastmilk substitutes when needed, based on proper awareness, and through proper marketing and distribution methods, and to encourage and support breastfeeding.

3. POLICY:

3.1 Support breastfeeding for the new mothers and lactating mothers
  3.1.1 Hospitals should provide adequate health support to hospitalized new mothers and newborns, even if rooming and breastfeeding dyad were not implemented or their separation was a must.
  3.1.2 Hospitals should provide the support needed to ensure the continuous breastfeeding among sick hospitalized mothers in all wards and departments and for young children in pediatric wards or departments, to ensure the continuation of breastfeeding.
  3.1.3 Inpatient and outpatient cases that require medical breastfeeding consultation shall be referred to professionally trained health practitioners specialized in breastfeeding and infant feeding within 24 -72 hours
  3.1.4 The health practitioner records breastfeeding and infants' nutrition history in the inpatient's file for each mother with a child below two years of age and records the counselling provided on breastfeeding and /or infant nutrition.
  3.1.5 All cases of insufficient breastmilk production shall be directly referred to a clinic specialized in breastfeeding counselling.
3.2 Requesting wet nurses for mother's incapable to breastfeed

3.2.1 Mothers or their families who were unable to breastfeed their child are referred to a social worker or a breastfeeding counsellor to discuss the possibility of hiring a wet nurse before they start feeding breastmilk substitute or event after starting it to minimize its use and the continuation on formula feeding

3.2.2 The wet nurse is referred to a breastfeeding specialist and infant feeding to give her appropriate counselling.

3.2.3 The parents' request and/or parent's consent for approval of wet nurses shall be recorded by the social worker in accordance with instructions given in this regard.

3.3 Breastmilk substitutes handling system:

3.3.1 The hospital is obligated to inform all health and non-health staff in the hospital to inform about of national code of breastmilk substitutes and its updated executive regulations

3.3.2 Violations of the breastmilk substitute's code committed by the private companies, health practitioners or hospital staff (according to the attached report form) are monitored, and subsequent legal measures are taken in this regard in accordance with the provisions of the code.

3.3.3 Breastfeeding promotion program shall be contacted in case of supporting the implementation of the process and its executive regulations.

4. PROCEDURE:

4.1 Types of breastmilk substitutes:

4.1.1 That the physician (neonatologist, pediatrician, and related specialties) determines the types and quantities of breast milk substitutes according to the hospital category and the previous statistics for them.

4.1.2 All types of breast milk substitutes should be supplied to hospitals

4.1.3 Priority should be given to ready-to-feed breast milk substitutes.

4.2 Supply and receipt:

4.2.1 Communication shall be direct with the medical supply in the Ministry of Health, the directorate, or the health assembly to secure breastmilk substitutes for hospitals without communicating with manufacturers
or agents in accordance with the system mentioned above and instructions

4.2.2 The secured breastmilk substitutes shall comply with the technical regulations and specification standard issued by Saudi Food and Drug Authority

4.2.3 Hospitals are prohibited from receiving breast milk substitutes free of charge (no cost) from manufacturers or suppliers directly and according to the regulations and instructions.

4.2.4 Safety and quality must be ensured when providing breast milk substitutes (product components - expirydate - method of use – the integrity of the packaging and product.....).

4.2.5 Breastmilk substitutes are shipped and transported in accordance with the requirements of technical regulations and Saudi specification standards

4.3 Breastmilk substitutes transport and storage chain in hospitals:

4.3.1 Breastmilk substitutes shall be stored in the hospital's warehouses and other sections in accordance with the Saudi regulations, specification standards, technical and health requirements

4.3.2 Packages of ready-made breastmilk substitutes delivered for newborns up to 6 months of age bearing the Saudi Ministry of Health logo and National Unified Procurement Company for medical supplies (NUPCO) solely

4.3.3 Receiving of breastmilk substitutes, cups and bottles shall be received by the medical supply at the hospital. Providing the production date less than third of its expiry period

4.3.4 Hospitals shall return the quantity received from the supplier in the event that the products are close to expiration or upon notice any violation of the terms and specifications, or a sign of damage, or defect or other things that affect the safety and quality of the product, and taking the necessary measures according to the system and the circulars (memos) regulating that.

4.4 Description and dispensing of breast milk substitutes:

4.4.1 In some cases that indicated special formula (the neonatologist or pediatrician or related health practitioner) prescribes the appropriate type of breastmilk substitute according to the health status

4.4.2 Medical indications for prescribing breast milk substitutes based on modern scientific research and evidence-based medicine

4.4.3 Prescription of breastmilk substitute shall be recorded in the infant's file, specifying whether temporary or permanent, as the mother is supported by breastfeeding substitutes, temporarily or permanently.

4.4.4 Breastmilk substitutes shall be given free of charge throughout the breastfeeding period for those with a proven medical need for all types and children up to 24 months of age (see the appendix for supply as recommended by Council of health insurance)

4.4.5 Powdered formula or milk is used only in the absence of ready to feed (RTF).

4.5 Milk Formula room (place) for powdered breast milk substitutes:

4.5.1 Powdered milk preparation to be a liquid is required at a place that contains the following:

4.5.1.1 There should be a special area isolated from the rest of the neighboring rooms for the preparation of breast milk substitutes.

4.5.1.2 The designated area must meet all health and technical requirements.

4.5.1.3 Surfaces in such designated sites ought to be clean and sanitized to prevent Enterobacter sakazakii and others microbes widely spread and grow on the surfaces designated for preparing infant feeding.

All equipment's or tools for preparing feedings, such as the bottle or cup, rings and nipples, should be cleaned and sterilized before using them.

It is preferable that the location of the room is close to the most frequently used departments or units, for example, maternity and children's hospitals near the neonatal intensive care unit. (see the reference)

4.6 Preparation of the powdered breastmilk substitutes:

4.6.1 When necessary and for special and rare medical cases, preparation is done inside the hospital under specific health controls and restrictions and high-quality safety precautions

4.6.2 Wash hands thoroughly (with soap and water for 40 seconds) or more from the hospital health care provider (or mother) before preparing or while providing breast milk substitutes to the infant.

4.6.3 When preparing powdered breastmilk substitutes, the following should be carried out to ensure the safety and quality of the product:

4.6.3.1 It is the exact milk described in the patient's file and concise to the standard specifications.

4.6.3.2 It is free from signs of spoilage or precipitation, and the package is also free from abnormal feature.

4.6.3.3 Using healthy water and ensuring, through concerned authorities, that the water is safe for drink

4.6.3.4 Water should first be boiled or heated to a temperature of no less than 70 degrees Celsius and then left to cool to room temperature (18-24) degrees Celsius.

4.6.4 Determine the amount of water first, then add the exact amount of powdered milk and mix it well to dissolve it in water - as it is written in the method of preparation on the product packaging label.

4.6.5 Preparations should only be heated when necessary, and the microwave should not be used for this.

4.6.6 Put an identification card on the prepared milk, including the patient's name (room or ward number), the name of the preparation, and the time and date of preparation

4.6.7 Powdered milk can is used after opening for a month only, provided that it is kept under an appropriate temperature (18-24 degrees Celsius).

4.6.8 The prepared liquid milk is utilized within two hours of its preparation

4.7 Health practitioner who is preparing the milk:

4.7.1 Should be one of the professional health practitioners (nursing - pharmacist - nutritionist).

4.7.2 Should have an experience in preparing formula or attended specialized training in this field.

4.7.3 Should adhere to clothing that prevents contamination of the prepared milk (headcover - mask - gloves).

4.8 Storing, transporting and handling of prepared milk:

4.8.1 If it is to be consumed within 2 hours of preparation, prepared milk can be kept in refrigeration where it can be kept only for 24 hours, with preserving the cooling temperature stable (4° - 8° C), recorded every 8 hours on a special label on the fridge door

4.8.2 In case of using the milk in various sections, rooms or intensive care sections, it is transferred as follows:

4.8.2.1 The milk should be transferred in bags or cold containers for a period not exceeding (30 minutes).

4.8.2.2 The milk should have the type, time, date and preservation degree written on it (Patient's name and room number) - if prepared for one patient

4.8.2.3 Prescribing the scientific name and not trademark that shows the manufacturer of the original products according to the Royal decree No. (333) dated on 9/8/1437 AH, and to be label to know the type of milk.

4.8.2.4 In cases of formula stored in fridge or transferred by cold bag, it should be heated for about 15 minutes and left to cool at room temperature (18 - 25 degrees Celsius) before use

4.8.2.5 Dispose of the prepared milk if it has been stored in the refrigerator for more than 24 hours or if it has been left out of the fridge for more than 2 hours

4.9 Taking samples of prepared milk

4.9.1 A sample is taken from each prepared milk and kept in a cool place (4°C) for at least 72 hours for reference when needed.

4.9.2 Hospitals' infection control departments shall take samples periodically and analyses them to ensure their safety.

4.9.3 The department mentioned above (or other sections that use the prepared milk) shall be reported in case there have been any notes after analyzing the sample

4.10 How to provide breastmilk substitutes for infants and young children:

4.10.1 Use the ready-to feed formula immediately after opening, within an hour of opening (see package label instructions).

4.10.2 Use powdered breastmilk substitutes immediately after preparation, within two hours of preparation and at an appropriate temperature (18 - 24 degrees Celsius), or for 24 hours if kept in the refrigerator

4.10.3 Provide the amount of milk upon demand and as approved by health practitioners (professional)

4.10.4 Milk can be provided for infants in different ways (cup, spoon, bottle or feeding tube), as approved by the health practitioners.

4.10.5 It is not preferable to use nipples when using breastmilk substitutes as an additional feeding for infants who are breastfed from their mothers due to the difference in jaw and tongue movement and rapid milk transfer with lack of self-control, this is to maintain breastfeeding.

4.11 Educating mothers and family members:

4.11.1 Health education shall be provided for each family, advised using breastmilk substitutes for every family member separately during each visit, with periodic follow-up. Education should contain the following topics:

4.11.1.1 Risks of non-breastfeeding for both the mother and the infant

4.11.1.2 Educating the mother whose infant child is hospitalized in hospitals and is fed on breastmilk substitutes on the proper use

4.12 Risks arising from breastmilk substitutes intake:

4.12.1 Any signs and symptoms suspected to be resulting from the use of breastmilk substitutes must be recorded in the medical file

4.12.2 In case of suspect a milk contamination, it should be stopped, and this should be documented in the medical file. An urgent report is submitted to the neonatal intensive care unit director, from there to the medical director, then to the hospital director, with a copy redirected to the hospital's medical supplies. The approved method for reporting shall be followed accordingly. An alternative milk from another manufacturer is used until the product's safety, and suitability for the infant are ascertained.

4.13 Policies and procedures of continuous professional education on breastmilk substitutes

4.13.1 This policy shall be circulated to all health practitioners involved in newborns, infants and young children care.

4.13.2 Health practitioners are trained to implement this policy.

4.13.3 Trained practitioners who have received training in infant and young child nurturing in the hospital shall undertake the clinical training and supervision of breastmilk substitutes usage for infants and children inpatients and outpatients in hospitals

4.13.4 Provide the update in scientific data on breastmilk substitutes without referring to the producing companies' pursuance of the Breastmilk Substitute Code and its Executive Regulations

4.14 The hospital is fully committed to compliance with the International Code of Marketing of Breast-milk Substitutes and the approved regulatory frameworks. Any practice that may directly or indirectly undermine the promotion of breastfeeding or encourage mothers to use breast-milk substitutes without a medical indication is strictly prohibited.

4.14.1 Reporting Violations

4.14.1.1 Any violation related to the following must be reported immediately:

4.14.1.1.2 Unauthorized interaction with company representatives

4.14.1.1.3 Distribution of samples or promotional materials

4.14.1.1.4 Reporting channels include:

4.14.1.4.1 Academic Affairs and Training Department

4.14.1.4.2 Quality and Patient Safety Department

4.14.1.4.3 Regulatory actions will be taken in accordance with the hospital's approved policies

4.14.1.4.4 Any violation must be reported immediately or reported to Security at 1179

5. MATERIALS AND EQUIPMENT:

N/A

6. RESPONSIBILITIES:

6.1 All Health Care Workers

6.2 Breastfeeding Department

7. APPENDICES:

7.1 Basic data for violator catcher forms

7.2 Request form for baby formula milk

8. REFERENCES:

8.1 ABM Clinical Protocol #3: Supplementary Feedings in the Healthy Term Breastfed Neonate, Revised 2017, Ann Kellams, Cadey Harrel, Stephanie Omage, Carrie Gregory, Casey Rosen-Carole.

8.2 Hale's Medications & Mothers' Milk 2021: A Manual of Lactational Pharmacology – An Essential Reference Manual on the Transmission of Medicine into Breast Milk

8.3 A guide to infant formula for parents who are bottle feeding, UNICEF, UK

8.4 Breast-milk Substitutes Marketing Saudi Code Executives Regulation (updated), 2019

8.5 Acceptable medical indications of breast milk substitutes, WHO and UNICEF, 2009

9. APPROVALS:

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Kingdom of Saudi Arabia
Hafar Al Batin Health Cluster
Maternity and Children Hospital

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

وصفة خاصة بصرف الحليب الصناعي للرضع
Request form for baby formula milk

Baby name اسم الطفل		D.O.B / تاريخ الولادة	
MRN / رقم الملف		Age / العمر	
WT / الوزن		Department / القسم	
Diagnosis / التشخيص			
Type of milk / نوع الحليب		Quantity / الكمية	
☐ عادي Regular ☐ خديج Preterm ☐ أخرى Other		(عدد القوارير)	
The medical reason for not using breast milk / السبب الطبي لعدم استخدام حليب الأم			
☐ أسباب متعلقة بالأم / Mother reasons ☐ أسباب متعلقة بالطفل / Baby reasons السبب / Reason: .... ☐ لا يوجد سبب طبي ولكن لا يتوفر حليب الأم / No medical cause but EBM not available ☐ أسباب أخرى / Other causes			

التاريخ / Date	التوقيع / Signed	الاسم / Name	
.....	.....	.....	الأخصائي المعالج Treating specialist
.....	.....	.....	الاستشاري المعالج Treating consultant

المملكة العربية السعودية
تجمع حفرالباطن الصحي

الـــرقـــم :.....
التـــاريخ: / / 14 هـ
المشفوعات:.....

محضر ضبط مخالفة لنظام تداول بدائل حليب الأم (تم ترجمته للغة الإنجليزية للإستفادة)
The form to catch the violators of national rules for marketing breast milk substitutes

التاريخ Date	الوقت Time	المدينة City	تحديد لموقع ضبط المخالفة Site of violation

Basic data for violator catcher البيانات الأساسية لمحرر المخالفات

الاسم Name	الرقم المدني / الإقامة I D Number	الجنسية Nationality	جهة العمل Place of work	رقم الجوال Mobile

وصف المخالفة : Describe the violation:

- .....
- .....
- .....
- .....

توقيع : المبلغ عن المخالفة :..... Signature: the violator catcher

اسم المخالف ..... name of the violators

الجهة التابع لها..... The violators Place of work

المذكور خالف منطوق المادة (.....) ونصها : the Mentioned violate article (.....), which say :

- .....
- .....
- .....

المذكور خالف منطوق البند رقم ( ) التي تتعلق ب : the Mentioned violate the rule ( ) that relate to

- .....
- .....
- .....
- .....

ملاحظة : يرفع المحضر مباشرة لمدير عام الشئون الصحية أو ما يقابلها في المؤسسات الصحية الاخرى وغيرها من الجهات (الوزارات و الهيئات الاخرى) ثم يرسل خطاب تغطية للمنسق الوطني لبرنامج الرضاعة الطبيعية رئيس لجنة النظر للمخالفات /المشرف العام على الإدارة العامة للتغذية بوزارة الصحة ص.ب 5253 الرياض 11422 هاتف4640811- فاكس 4645536

Note: to send the form directly to the Director General of Health Affairs or its equivalent in other health centers and other (ministries) and then sends with a cover letter to the coordinator of the National Program of breastfeeding / Supervisor of General Department of Nutrition, Ministry of Health
p.o. Box 5253 Riyadh 11422 Tel 4,640,811 - 4,645,536 Fax