

TITLE

PASTEURIZED DONOR HUMAN MILK

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NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

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OBJECTIVES

- To outline the conditions recommended for prescribing pasteurized **donor human milk (DHM)** for infants, based on current evidence, in Alberta Health Services (AHS) Neonatal Intensive Care Unit (NICU) settings.
- To identify the required processes for ordering, storage, retrieval, labelling, preparation, addition of additives, verification, and feeding of DHM in AHS NICU settings.

PRINCIPLES

AHS NICU settings promote the health and well-being of infants and **guardians**, based on the best available evidence, and subject to the preferences and values of the infant's guardian(s).

The systems and processes within AHS NICU settings prioritize the needs of the infant and their guardian(s) by keeping their needs and perspectives at the heart of every health care encounter. Individual patients exist within particular contexts and social relationships that can impact how best to interpret their preferences and well-being.

In the NICU, a guardian's **informed feeding decision** occurs following consultation and information provision from **health care providers**. **Breastmilk** is the healthiest option for infant feeding, when available. Health care providers should promote the use of breastmilk for infants within an informed feeding decision perspective, and approach this issue with sensitivity as some individuals may wish to provide breastmilk but may be unable to do so.

AHS provides a safe source of pasteurized DHM obtained from an accredited human milk bank which follows guidelines set by the Human Milk Banking Association of North America (HMBANA). Lactating individuals who donate their breastmilk to human milk banks must meet

rigid screening criteria that includes a medical and lifestyle history, blood testing for HIV, HTLV I and II, hepatitis B and C, and syphilis. DHM is pasteurized and cultured post pasteurization to ensure safety, and is frozen for storage and transported as per HMBANA guidelines.

Provision of DHM based on established conditions for use encourages equitable access. Infants born premature, with growth restrictions, or with compromised gut perfusion are at additional risk for serious consequences like necrotizing enterocolitis (NEC). DHM access is prioritized to those who are most likely to suffer a serious consequence without human milk feedings, in order to achieve equitable health outcomes.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. Points of Emphasis

- 1.1 The **most responsible health practitioner (MRHP) or health care professional** delegated by the MRHP shall obtain informed consent from the infant's guardian(s) for the provision of DHM to the infant, in accordance with the *AHS Consent to Treatment/Procedure(s) Policy Suite*.
 - a) As part of the informed consent process, education shall be provided on the source of DHM (i.e., HMBANA human milk bank), pasteurization and screening process, rationale for use, and risk of poor growth.
- 1.2 An order or prescription from the MRHP is required for providing DHM.
- 1.3 DHM should be fortified in order to meet the preterm infants' high nutrient needs. Preterm infants who are fed unfortified DHM have poor weight gain and length growth. Even when fortified, DHM does not always support adequate growth due to its lower nutrient content relative to breastmilk.

Exception: Infants receiving parenteral nutrition and DHM simultaneously may not require the DHM to be fortified. Protein needs can be adequately provided by the parenteral nutrition. Calcium and phosphorus provision, however, are sub-optimal in parenteral nutrition and low in breastmilk relative to a preterm infant's needs, so DHM should be fortified with these minerals.

- 1.4 The appropriate amount of DHM for each infant feeding shall be determined by the health care team, based on the infant's feeding tolerance and growth needs over a period of time. Refer to Appendix A: *Weight Gain Velocity* for the recommended formula to calculate weight gain velocity for preterm infants.

2. Conditions for Prescribing Pasteurized Donor Human Milk (DHM)

- 2.1 If breastmilk is not available, evidence suggests that infants with the following conditions may benefit from DHM, by decreasing the incidence of NEC (see summary of below conditions in Appendix B: *Conditions for Pasteurized Donor Human Milk [DHM] Prescribed in the NICU*):
- a) infants born less than 32^{0/7} weeks gestation until the infant is 32^{6/7} weeks gestational age, or the infant is at least 14 days of age;
 - (i) If appropriate weight gain velocity (see Appendix A: *Weight Gain Velocity*) is not achieved with fortified DHM, the health care team may consider discontinuing DHM and transitioning the infant to an appropriate infant formula.
 - b) infants born between 32^{0/7} to 33^{6/7} weeks gestational age, when DHM is intended as a bridge to breastmilk for a maximum of five (5) days;
 - c) infants of any gestation at birth with one (1) of the following criteria:
 - (i) less than the tenth percentile weight-for-age and admitted to the NICU; or
 - (ii) confirmed or suspected cocaine use by the individual who gave birth to the infant;
 - Infants exposed to cocaine during the pregnancy are at a higher risk for NEC. Due to this exposure, infants may benefit from the use of DHM if breastmilk is not available.
 - Health care providers shall exercise caution and clinical judgement for suspected cocaine use to avoid the possibility of judgement or stereotypes, based on social or other factors. Unfounded accusations may cause harm to the therapeutic relationship between the individual and health care providers.
- Note:** DHM could be used until the infant is at least 14 days of age, as long as weight gain velocity is adequate.
- d) infants diagnosed with:
 - (i) intestinal failure or at high risk of intestinal failure. DHM may be used until tolerating transition to formula at full fluid intake or until DHM is unable to support adequate growth;
 - (ii) congenital heart disease in conditions associated with poor gut perfusion. DHM may be used until tolerating full enteral feed volume for 48 hours, or for at least seven (7) days, whichever is later;

- (iii) partial or complete exchange transfusion or intravenous immune globulin (IVIG) treatment, when intended as a bridge to breastmilk for a maximum of three (3) days; or
- (iv) hypoxic ischemic encephalopathy (HIE) if the infant is fed during cooling and up to five (5) days after rewarming;
- e) infants ready to begin enteral feeds post confirmed NEC Bell's stage II or greater until:
 - (i) the infant has tolerated full enteral feed volume for at least 48 hours; or
 - (ii) is at least 14 days of age.

Note: The risk of NEC and the risk of growth failure must be considered.

- 2.2 Clinical judgement should be exercised when prescribing DHM outside of the conditions outlined in Section 2.1 above. If a deviation from these conditions is determined to be appropriate or necessary, then documentation of the rationale shall be included on the infant's **health record**.
- 2.3 Guardian(s) who are interested in obtaining DHM for their infant but their infant does not meet the conditions outlined in Section 2.1 above, may choose to obtain DHM on their own, for the purpose of feeding their infant.
 - a) Guardians are responsible to provide documentation from an approved source (i.e., HMBANA-approved human milk bank) indicating that the DHM has been properly collected, stored, pasteurized, and cultured in accordance with the Canadian Food Inspection Agency.

3. Placing a Product Order for Pasteurized Donor Human Milk (DHM)

- 3.1 A designated health care provider shall be responsible for placing a product order for DHM from an HMBANA-approved human milk bank.
 - a) The closest HMBANA-approved human milk bank in Alberta is NorthernStar Mothers Milk Bank in Calgary. Each NICU setting that provides DHM requires an AHS standing purchase order to order DHM from NorthernStar Mothers Milk Bank.
- 3.2 To obtain DHM from NorthernStar Mothers Milk Bank, the designated health care provider shall include the following information on the product order:
 - a) amount of milk required;
 - b) specific location where milk is to be shipped (hospital and unit); and
 - c) name of the designated health care provider who is responsible to receive the milk.

- 3.3 When DHM arrives at the facility, the designated health care provider shall:
- a) complete the receiving form provided and verify the condition of each container of DHM;
 - (i) DHM containers should be intact with no damage evident, in a frozen state, and should match the product order (i.e., the number of bottles and batch numbers should match the packing slip).
 - (ii) If any containers are not solidly frozen, are damaged when received, or do not match the product order, then the designated health care provider shall refuse the DHM and the DHM shall be returned to the NorthernStar Mothers Milk Bank. The designated health care provider shall notify the NorthernStar Mothers Milk Bank if replacement of the product is required.
 - b) store the DHM after inspection immediately in the designated freezer; and
 - c) place the original copy of the receiving form in a designated location, in accordance with the *AHS Records Retention Schedule*.

4. Recording Pasteurized Donor Human Milk (DHM) Batch Numbers

- 4.1 When a container of DHM is used for an infant, the health care provider shall record the DHM batch number in the infant's health record.

5. Storage of Pasteurized Donor Human Milk (DHM)

- 5.1 DHM shall be stored immediately in accordance with the *AHS Breastmilk Safe Management Procedure*.
- 5.2 DHM shall be discarded if the temperature of the storage unit deviates from the temperature requirements outlined in *Appendix C: Storage Requirements and Usage of Pasteurized Donor Human Milk (DHM) in Hospitals*.

6. Retrieving, Thawing, Labelling, Warming, Verifying, and Feeding Pasteurized Donor Human Milk (DHM)

- 6.1 Retrieving DHM
- a) In preparation for feeding, the health care provider shall perform hand hygiene as per the *AHS Hand Hygiene Policy and Procedure* and retrieve the DHM from the designated refrigerator or freezer.
 - b) The health care provider shall verify the label and expiry date on the DHM container, and confirm and record the batch number for inventory tracking purposes.

6.2 Thawing DHM

- a) Frozen DHM shall be thawed in accordance with the AHS *Breastmilk Safe Management* Procedure.
- b) If the DHM will not be used immediately, then the health care provider shall re-refrigerate the DHM before it is completely thawed (i.e., while ice crystals are still present).
 - (i) If the DHM has fully thawed, then it shall be fed or discarded within 48 hours of being stored in the refrigerator.
 - (ii) In the absence of ice crystals, DHM is considered to be fully thawed and shall not be refrozen.
 - (iii) If the DHM has become partially thawed (less than 50% thawed) and there are ice crystals within the container, then the DHM may be refrozen.

6.3 Labelling DHM

- a) Health care providers shall label patient-specific DHM containers with the product name (i.e., DHM), DHM batch number, infant's first and last name, birth date, and hospital identification number, and where available, a label generated from the **bar code scanning system**.

6.4 DHM shall be warmed, verified, and fed in accordance with the AHS *Breastmilk Safe Management* Procedure.

7. Enteral Feedings

7.1 DHM shall be enterally fed in accordance with the AHS *Breastmilk Safe Management* Procedure.

8. Pasteurized Donor Human Milk (DHM) with Additives

8.1 DHM with additives shall be **independently double-checked**, prepared, verified, labelled, and stored in accordance with the AHS *Breastmilk Safe Management* Procedure.

9. Guardian Education

9.1 When DHM has been selected as the feeding option within an informed feeding decision, health care professionals shall educate the guardian(s) regarding the safe management of DHM. This shall, whenever possible:

- a) occur upon admission and orientation to the care unit; and
- b) be reinforced throughout the hospital stay.

- 9.2 Verbal education for the guardian(s) shall be enhanced with printed materials (as available), including:
- a) the importance of providing breastmilk whenever possible, for the infant's health;
 - b) contact information for accredited human milk banks;
 - c) safe preparation, handling, and storage of DHM in order to minimize adverse events;
 - d) how to safely feed DHM while their infant is in hospital;
 - e) the bar code scanning system (where available);
 - f) the importance of verifying the accuracy of the DHM being fed to the right infant; and
 - g) the importance of the guardian(s) advising a health care professional if their infant was given unintended DHM (considered a **clinical adverse event**) or if there was a **close call**.
- 9.3 While providing education, health care professionals shall:
- a) encourage questions and engage with the guardian(s) and families, as appropriate;
 - b) assess for understanding (e.g., ask the guardian[s] to explain the provided education in their own words and practices) and the need for reinforcement/further teaching; and
 - c) be sensitive and aware of potential challenges to family care related to cultural, language, and literacy differences.

10. Clinical Adverse Events or Close Calls

- 10.1 If a close call or clinical adverse event occurs with DHM, the health care provider shall refer to the AHS *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events* Policy Suite.
- a) If an infant receives DHM unintentionally, the health care provider shall also refer to the AHS *Breastmilk Safe Management: When an Infant Unintentionally Receives Incorrect Breastmilk* Procedure for guidance.

11. Documentation

- 11.1 Health care professionals shall document the following information in the infant's health record:

- a) the informed consent process, in accordance with the AHS *Consent to Treatment/Procedure(s)* Policy Suite;
- b) the date, time, and signatures of the two (2) verifiers who completed the **double-check** prior to feeding;
 - (i) If the bar code scanning system label was used, the health care professional shall indicate this in the infant's health record.
- c) the date, time, and signatures of the two (2) health care professionals who performed the independent double-check, when additives were mixed in DHM (as per the AHS *Independent Double-Check* Guideline);
- d) all feedings administered, including information on feeding type (DHM or DHM with additives), route (oral [bottle, syringe] or enteral), volume administered per route, and the DHM batch number(s);
- e) all guardian education related to DHM; and
- f) facts specific to a DHM-related clinical adverse event or close call as per the AHS *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events* Policy Suite.

- 11.2 The most appropriate health care professional may submit a report in the Reporting and Learning System for Patient Safety (RLS), as per the AHS *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events* Policy Suite, for both DHM-related clinical adverse events and close calls.

DEFINITIONS

Bar code scanning system means the unique bar code applied to donor human milk containers, validating the correct milk is being fed to the correct infant and verifying the contents have not expired or were meant for another infant.

Breastmilk means breastmilk coming from the infant's birth parent; this includes antenatal colostrum (colostrum that is expressed and collected during pregnancy).

Clinical adverse event (CAE) means an event that reasonably could or does result in an unintended injury or complications arising from health care management, with outcomes that may range from (but are not limited to) death or disability to dissatisfaction with health care management, or require a change in patient care.

Close call means an event that has potential for harm and is intercepted or corrected prior to reaching the patient.

Donor human milk (DHM) means human milk that is pasteurized and cultured post pasteurization by a Human Milk Banking Association of North America (HMBANA) approved milk bank to ensure safety after collection from a lactating individual who has met rigid screening criteria, including a medical and lifestyle history, blood testing for HIV, HTLV I and II,

hepatitis B and C, and syphilis. The pasteurized donor human milk is frozen for storage and transported as per HMBANA guidelines.

Double-check means a verification process to ensure the infant receives the correct donor human milk. It occurs prior to feeding donor human milk to an infant, whereby a health care professional, at the infant's bedside, matches two (2) or more patient identifiers (as per the AHS *Patient Identification Policy*) on the donor human milk container label with the information on the infant's patient identification band with another health care professional, a health care provider, or the bar code scanning system.

Guardian means, where applicable:

For a minor: a guardian as defined by the *Family Law Act* (Alberta), a divorced parent with custody of the minor, or a person appointed pursuant to a will, personal directive, court order, agreement or by authorization of legislation (e.g., *Child, Youth and Family Enhancement Act* [Alberta]).

For an adult: an individual appointed by the Court in accordance with the *Adult Guardianship and Trusteeship Act* (Alberta) to make decisions on behalf of the adult patient when the adult patient lacks capacity.

Health care professional means an individual who is a member of a regulated health discipline, as defined by the *Health Professions Act* (Alberta), and who practices within scope and role.

Health care provider means any person who, within their role, provides goods or services to a patient, inclusive of health care professionals, staff, students, volunteers and other persons acting on behalf of or in conjunction with Alberta Health Services.

Health record means the collection of all records documenting individually identifying health information in relation to a single person.

Independent double-check means a verification process whereby a second health care professional conducts a verification of another health care professional's completed task. The most critical aspect is to maximize the independence of the double-check by ensuring that the first health care professional does not communicate what they expect the second health care professional to see, which would create bias and reduce the visibility of an error.

Informed feeding decision means a feeding decision that takes place when a guardian decides how to feed their child. Informed feeding decisions are influenced by various caregivers and supporters who contribute to the decision-making process. However, decisions regarding breastfeeding shift the decision-making power into the sphere of the individual whose body is required to breastfeed or to express their milk. The guardian is enabled to make an informed feeding decision when:

- they have information about the feeding options, their health benefits, safety issues, health risks, and relevant contextual factors;
- they have the opportunity to express relevant values, preferences and circumstances for themselves and their family; and

- the information provided is responsive and sensitive to the context of the guardian and their infant/child, is evidence-informed and objective.

Most responsible health practitioner (MRHP) means the health practitioner who has responsibility and accountability for the specific treatment/procedure(s) provided to a patient and who is authorized by AHS to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of their practice.

REFERENCES

- Appendix A: *Weight Gain Velocity*
- Appendix B: *Conditions for Pasteurized Donor Human Milk (DHM) Prescribed in the NICU*
- Appendix C: *Storage Requirements and Usage of Pasteurized Donor Human Milk (DHM) in Hospitals*
- Alberta Health Services Governance Documents:
 - Breastmilk Safe Management Policy (#PS-16)*
 - Breastmilk Safe Management Procedure (#PS-16-01)*
 - Breastmilk Safe Management: When an Infant Unintentionally Receives Incorrect Breastmilk Procedure (#PS-16-02)*
 - Consent to Treatment/Procedure(s) Policy Suite (#PRR-01)*
 - Hand Hygiene Policy (#PS-02)*
 - Hand Hygiene Procedure (#PS-02-01)*
 - Independent Double-check Guideline (#PS-60-01)*
 - Invasive Infusion Line and Tubing Verification Policy (#PS-15)*
 - Patient Identification Policy (#PS-06)*
 - Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy Suite (#PS-95)*
 - Records Retention Schedule (#1133-01)*

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APPENDIX A

Weight Gain Velocity

Growth assessments are most informed by examining both the placement and growth history on an appropriate growth chart, but over the short-term, calculation of weight gain velocity can aid the assessment of nutrient adequacy. Weight gain velocity should not be calculated for periods shorter than five (5) to seven (7) days, since day-to-day weight fluctuations inflate errors in shorter-term estimates.

The following formula is recommended for weight gain velocity:

Weight change in grams (g) ÷ $\frac{\text{average of start and end weights in kilograms [kg]}}{\text{number of days (d)}}$

Note: Preterm infant adequate weight gain velocity is considered to be 15 to 20 g/kg/day after the postnatal weight loss phase and up to 36 weeks gestation. After 36 weeks gestation, the expected growth velocity begins to decrease.

APPENDIX B

Conditions for Pasteurized Donor Human Milk (DHM) Prescribed in the NICU

Condition Details	Duration of DHM
	<i>Unless otherwise stated, discontinue DHM when:</i> <ul style="list-style-type: none"> <input type="checkbox"/> <i>Breastmilk is available <u>or</u></i> <input type="checkbox"/> <i>Weight gain velocity is inadequate for gestation and age</i>
Prematurity	
Infants born less than 32 ^{0/7} weeks gestation	<ul style="list-style-type: none"> <input type="checkbox"/> Until 32^{6/7} weeks <u>or</u> <input type="checkbox"/> Is at least 14 days of age
Infants born between 32 ^{0/7} to 33 ^{6/7} weeks gestation	<input type="checkbox"/> Bridging for a maximum of five (5) days
Clinical indications for infants of any gestation	
Infants with a birth weight less than the 10 th percentile and admitted to the NICU	<input type="checkbox"/> Is at least 14 days of age
Confirmed or suspected cocaine use by the individual who gave birth to the infant	
Intestinal failure or at high risk of intestinal failure	<input type="checkbox"/> Tolerating transition to formula at full fluid intake
Congenital heart disease in conditions associated with poor gut perfusion	<input type="checkbox"/> Tolerating full enteral feed volume for 48 hours, or for at least seven (7) days, whichever is later
Partial or complete exchange transfusion	<input type="checkbox"/> Bridging for a maximum of three (3) days
Intravenous immune globulin (IVIG) treatment	
Hypoxic ischemic encephalopathy (HIE)	<input type="checkbox"/> When the infant is fed during cooling <u>and</u> up to five (5) days after rewarming
Ready to begin enteral feeds post confirmed NEC Bell's stage II or greater	<ul style="list-style-type: none"> <input type="checkbox"/> Tolerating full enteral feed volume for at least 48 hours <u>or</u> <input type="checkbox"/> Is at least 14 days of age

If a deviation from these conditions is determined to be appropriate or necessary, then documentation of the rationale shall be included on the infant's health record.

APPENDIX C

Storage Requirements and Usage of Pasteurized Donor Human Milk (DHM) in Hospitals

State of DHM	Location	Temperature	Storage Duration
Frozen DHM	Freezer with door inside the door of a refrigerator	Less than 0°C	2 weeks
	Freezer attached to a refrigerator with separate door	Less than 0°C	3 months
	Deep freezer	-18°C to -20°C	NICU: 6 months Non-NICU: 12 months
Thawed DHM*	Refrigerator	0°C to 4°C	Feed DHM or discard after <u>48 hours</u>
Thawed DHM with Additives*	Refrigerator	0°C to 4°C	Feed DHM or discard after 24 hours
	Room temperature	15°C to 20°C	Feed DHM or discard after 4 hours. Preferably kept in refrigerator until time to warm and feed.

* Do not refreeze.

* If DHM has become partially defrosted due to freezer failure and there are still ice crystals within the container, the DHM is only partially thawed (less than 50% thawed) so the DHM can be refrozen.

In the absence of ice crystals, DHM has completely thawed and shall not be refrozen.

If DHM has fully thawed, it shall be fed or discarded within 48 hours of being stored in the refrigerator.

If DHM has fully thawed and has been fortified with additives, it shall be fed or discarded within 24 hours of being stored in the refrigerator.