TITLE

BREASTMILK SAFE MANAGEMENT: WHEN AN INFANT UNINTENTIONALLY RECEIVES INCORRECT BREASTMILK

OBJECTIVES

- To outline consistent steps to follow when an infant unintentionally receives incorrect breastmilk in an Alberta Health Services (AHS) Acute Care setting.

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 For the safe management of donor human milk, health care providers shall follow the AHS Pasteurized Donor Human Milk Procedure.

1.2 This Procedure uses the term ‘source person’ to refer to the individual who is the source of the incorrect breastmilk that the infant unintentionally receives.

1.3 This Procedure uses the term ‘birth parent’ to refer to the individual who gave birth to the infant and produces breastmilk that is given to the infant. For the purposes of this Procedure, the birth parent may or may not be the infant’s legal guardian.
2. Clinical Adverse Event (CAE)

2.1 When an infant unintentionally receives incorrect breastmilk from a source person, a clinical adverse event (CAE) has occurred.

2.2 To guide practice in the event of a CAE, refer to:

   a) Appendix A: When an Infant Unintentionally Receives Incorrect Breastmilk Flowchart for a visual representation of the roles and responsibilities of those involved in the CAE process;

   b) AHS Checklist - Breastmilk Safe Management: When an Infant Unintentionally Receives Incorrect Breastmilk to assist with tracking the CAE process (this may be found on Insite); and

   c) AHS Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy Suite.

3. Confidentiality

3.1 Confidentiality shall be maintained at all points throughout the CAE process, including disclosure, counselling, blood testing, informing, treatment/follow-up, and documentation.

   a) The identity of the source person, the birth parent, the infant’s guardian(s), and the infant shall be protected and not disclosed to each respective party by any health care provider at any point throughout the CAE process, in compliance with the Health Information Act (Alberta) and the Public Health Act (Alberta).

4. Notification and Disclosure

4.1 Upon realizing that an infant has unintentionally received the incorrect breastmilk:

   a) the health care professional shall immediately notify the Charge Nurse; and

   b) the Charge Nurse shall:

      (i) immediately notify the infant’s most responsible health practitioner (MRHP); and

      (ii) notify the Unit Manager.

4.2 The infant’s MRHP shall disclose the facts of the breastmilk CAE to the source person and the infant’s guardian(s), in a manner consistent with Section 3.1 above, and the AHS Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy Suite.
4.3 In the event of a close call where the potential for a breastmilk CAE could have occurred, the health care professional who discovered the close call shall notify the Charge Nurse, who shall then notify the Unit Manager.

5. Counselling and Support

5.1 The infant’s MRHP shall provide specific counselling, in a manner consistent with Section 3.1 above, to the source person, the birth parent, and the infant’s guardian(s).

5.2 Counselling for the source person shall include awareness of the following:

a) the potential risk of transmission of a blood borne virus to the infant, as identified, if applicable, from the results of the source person’s:

(i) AHS Source Person’s Risk of Infection Assessment Form;

(ii) health record review; and/or

(iii) blood tests;

b) the need to obtain informed consent (see Section 6.1 below):

(i) to complete the AHS Source Person’s Risk of Infection Assessment Form;

(ii) to review the source person’s health record, if:

• the source person refuses the completion of the AHS Source Person’s Risk of Infection Assessment Form; and/or

• additional health information is required;

(iii) for blood testing;

• All informed consent shall include the need to disclose the source person’s identifying personal information and results to the infant’s MRHP, and the non-identifying results to the infant’s guardian(s).

c) the need for the infant’s MRHP to contact the source person’s MRHP if blood testing occurs (see Section 8 below), to advise, in a manner consistent with Section 3.1 above, of the:

(i) breastmilk CAE;

(ii) completion of the AHS Source Person’s Risk of Infection Assessment Form, if applicable;

(iii) review of the source person’s health record, if applicable; and/or
(iv) completion of the source person’s lab requisition and the need for the source person’s MRHP to:

- review the source person’s blood test results;
- provide follow-up counselling and treatment to the source person, as appropriate; and
- notify the Medical Officer of Health (MOH) if any reportable blood borne viruses are identified in the source person’s blood test results, in accordance with the Public Health Act (Alberta).

5.3 Counselling for the infant’s guardian(s) shall include awareness of the following:

a) the potential risk of transmission of a blood borne virus to the infant, as identified, if applicable, from:

   (i) the results of the source person’s:

      - AHS Source Person’s Risk of Infection Assessment Form;
      - health record review; and/or
      - blood tests;

   (ii) the results of the birth parent’s blood tests (see Section 5.4 below);

b) the potential to blood test the infant (see Section 8.3 below), and if applicable, the need to obtain the guardian’s informed consent for blood testing (see Section 6.4 below), as per the AHS Consent to Treatment/Procedure(s) Policy Suite; and

c) the potential need for the infant to require treatment, dependent on the results of the:

   (i) source person’s AHS Source Person’s Risk of Infection Assessment Form, if applicable;
   (ii) review of the source person’s health record, if applicable;
   (iii) source person’s blood tests;
   (iv) birth parent’s blood tests; and/or
   (v) infant’s blood tests, if applicable.
5.4 Counselling for the birth parent shall include awareness of the following:

a) the need to obtain informed consent (see Section 6.2 below) for blood testing of the birth parent, which includes consent to disclose identifying results to the infant’s MRHP and the infant’s guardian(s);

   (i) The birth parent’s blood test results are used as a baseline assessment for the infant, due to the potential risk of transmission of blood borne viruses during birth and/or from breastfeeding.

b) the need for the infant’s MRHP to contact the birth parent’s MRHP, if blood testing occurs (see Section 8 below), to advise, in a manner consistent with Section 3.1 above, of the:

   (i) breastmilk CAE; and

   (ii) completion of the birth parent’s lab requisition and the need for the birth parent’s MRHP to:

         • review the birth parent’s blood test results;

         • provide follow-up counselling and treatment to the birth parent, as appropriate; and

         • notify the MOH if any reportable blood borne viruses are identified in the birth parent’s blood test results, in accordance with the Public Health Act (Alberta).

5.5 The clinical leader shall offer support to staff, midwifery staff, and medical staff involved in the breastmilk CAE, as appropriate, in accordance with the AHS Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy Suite.

6. **Obtaining Informed Consent**

6.1 The infant’s MRHP shall obtain informed consent from the source person:

a) to complete the AHS Source Person’s Risk of Infection Assessment Form (see Section 7.3 below), as per the AHS Consent to Treatment/Procedure(s) Policy Suite;

   (i) The infant’s MRHP shall use the AHS Consent to Treatment Plan or Procedure Form if written consent is chosen to complete the AHS Source Person’s Risk of Infection Assessment Form.

   (ii) The infant’s MRHP shall ensure the verbal consent discussion includes, or the written consent identifies, that the purpose of completing the AHS Source Person’s Risk of Infection Assessment Form...
Assessment Form is to determine the risk of transmission of a blood borne virus to the infant and to treat the infant, if applicable.

b) to review the source person’s health record, if the source person refuses the completion of the AHS Source Person’s Risk of Infection Assessment Form, and/or if additional health information is required, and to disclose the source person’s identifying personal information and results to the infant’s MRHP and the source person’s non-identifying results to the infant’s guardian(s) (see Section 7.4 below);

(i) The infant’s MRHP shall use the AHS Consent to Disclose Health Information Form to obtain written consent to review the source person’s health record (see Section 7.4 below).

- The infant’s MRHP shall ensure the AHS Consent to Disclose Health Information Form identifies that the health record will be reviewed to determine the risk of transmission of a blood borne virus to the infant and to treat the infant, if applicable.

(ii) The infant’s MRHP shall use the same AHS Consent to Disclose Health Information Form to obtain written consent to disclose the results from the AHS Source Person’s Risk of Infection Assessment Form and/or the review of the source person’s health record to the:

- infant’s MRHP, ensuring the AHS Consent to Disclose Health Information Form states that the source person’s identifying personal information and results will be disclosed to the infant’s MRHP to confirm the risk of transmission of a blood borne virus to the infant and to treat the infant, if applicable; and

- infant’s guardian(s), in a manner consistent with Section 3.1 above, ensuring the AHS Consent to Disclose Health Information Form states that the source person’s non-identifying health information will be disclosed to the infant’s guardian(s) for the purpose of their awareness of the potential risk of transmission of a blood borne virus to the infant and to treat the infant, if applicable.

c) for blood testing and to disclose the blood test results (see Section 8 below) using the AHS Consent to Blood Testing for Blood Borne Viruses Form, ensuring the informed consent discussion includes:

(i) the purpose of blood testing is to identify the risk of transmission of a blood borne virus to the infant and to treat the infant, if applicable; and
(ii) consent from the source person to have the source person’s:

- identifying personal information and blood test results disclosed to the infant’s MRHP, for the purpose of “matching” the results to the infant and for treatment of the infant, if applicable; and

- non-identifying blood test results disclosed to the infant’s guardian(s) for the purpose of their awareness and to treat the infant, if applicable.

6.2 The infant’s MRHP shall obtain informed consent from the birth parent:

a) for blood testing (see Section 8 below), using the AHS Consent to Blood Testing for Blood Borne Viruses Form and ensuring the informed consent discussion identifies that the purpose of blood testing is to establish a baseline for the infant and to treat the infant, if applicable;

b) to disclose the birth parent’s blood test results to the infant’s guardian(s), ensuring the AHS Consent to Disclose Health Information Form identifies that the purpose is for the infant’s guardian(s) to be aware of the risk of transmission of a blood borne virus to the infant and to treat the infant, if applicable.

6.3 If the source person refuses to consent to completion of the AHS Source Person’s Risk of Infection Assessment Form, review of the source person’s health record, and blood testing, and/or if the birth parent refuses to consent to blood testing, the infant’s MRHP shall contact a Pediatric Infectious Diseases Specialist (see Section 7.1 c) below), and shall inform the infant’s guardian(s).

6.4 The infant’s MRHP shall obtain informed consent from the infant’s guardian(s) for the infant’s blood testing, if applicable (see Sections 8.3 and 8.4 below), using the AHS Consent to Treatment Plan or Procedure Form, as per the AHS Consent to Treatment/Procedure(s) Policy Suite.

7. Risk of Infection Assessment

7.1 There are resources available to assist in the risk of infection assessment process. These resources may include, but are not limited to:

a) the AHS Source Person’s Risk of Infection Assessment Form;

b) the source person’s health record; and
c) Infectious Diseases Specialists.

(i) Pediatric Infectious Diseases Specialists may be reached in:

- Calgary, through the Alberta Children’s Hospital Switchboard; or
- Edmonton, through the Stollery Children’s Hospital Switchboard.

(ii) If Infectious Diseases Specialists are not available, contact a Neonatal/Pediatric Specialist, the MOH, and/or an Infection Prevention and Control practitioner, based on need and/or availability.

7.2 The infant’s MRHP shall explain the risk of infection assessment process to the source person. This is usually done during disclosure of the breastmilk CAE.

7.3 If the source person agrees to proceed with completion of the AHS Source Person’s Risk of Infection Assessment Form, the infant’s MRHP shall:

a) obtain informed consent from the source person (see Section 6.1 a) above);

b) complete the AHS Source Person’s Risk of Infection Assessment Form; and

c) review the results from the AHS Source Person’s Risk of Infection Assessment Form and disclose the results, in a manner consistent with Section 3.1 above, to the infant’s guardian(s).

7.4 If the source person refuses the completion of the AHS Source Person’s Risk of Infection Assessment Form and/or if additional health information is required, the infant’s MRHP shall:

a) obtain informed consent from the source person for the infant’s MRHP to review the source person’s health record (see Section 6.1 b) above);

b) review the source person’s health record; and

c) disclose the non-identifying results of the health record review, in a manner consistent with Section 3.1 above, to the infant’s guardian(s).

8. Blood Testing

8.1 The infant’s MRHP may recommend blood testing, independent of the results from the AHS Source Person’s Risk of Infection Assessment Form and/or review of the source person’s health record, to the:
a) source person; and

b) birth parent.

8.2 If the source person and/or the birth parent agrees to blood testing, the infant’s MRHP shall obtain informed consent using the AHS Consent to Blood Testing for Blood Borne Viruses Form (see Sections 6.1 c) and 6.2 a) above).

8.3 The infant’s MRHP may recommend blood testing for the infant, dependent on the decision to provide or refuse consent, and/or the results of:

a) the source person’s:
   (i) AHS Source Person’s Risk of Infection Assessment Form;
   (ii) health record review; and/or
   (iii) blood test;

b) the birth parent’s blood test.

8.4 The infant’s guardian(s) may request the infant receive blood testing, independent of the decision to provide or refuse consent, and/or the results of:

a) the source person’s:
   (i) AHS Source Person’s Risk of Infection Assessment Form;
   (ii) health record review; and/or
   (iii) blood test;

b) the birth parent’s blood test.

8.5 If the decision is made to blood test the infant, the infant’s MRHP shall obtain informed consent from the infant’s guardian(s) (see Section 6.4 above), as per the AHS Consent to Treatment/Procedure(s) Policy Suite.

8.6 If informed consent is obtained (as per Sections 6.1 c), 6.2 a), and 6.4 above), the infant’s MRHP shall use the Blood and Body Fluid Exposure Testing Requisition Form (Alberta Provincial Laboratory for Public Health) to request the blood testing and shall:

a) ensure it is drawn and sent STAT;

b) check off the applicable box to indicate if the blood specimen is from the “Source Person (BBFE)” or the “Recipient/Exposed Person (BBFE)”:
(i) The “Source Person (BBFE)” on this Form is the source person or the birth parent; the “Recipient/Exposed Person (BBFE)” is the infant.

(ii) Both of the above applicable boxes will include the following tests:

- HIV antibody;
- hepatitis B surface antigen (HBsAg);
- hepatitis B surface antibody (HBsAb); and
- hepatitis C (HCV) antibody.

c) add HTLV-I and HTLV-II antibodies to the Blood and Body Fluid Exposure Testing Requisition Form, if the source person or birth parent is from an endemic area (Japan, Caribbean countries, sub-Saharan Africa, and Nunavut);

d) add CMV IgG to the Blood and Body Fluid Exposure Testing Requisition Form, if the infant is less than 34 weeks gestation and/or less than 1500 grams birth weight; and

e) include the name of the infant’s MRHP, as well as the source person’s or birth parent’s MRHP’s name, on the respective individual’s requisitions.

8.7 If the source person or the birth parent is an inpatient, blood testing shall be completed by the inpatient lab team.

8.8 If the source person or the birth parent is not an inpatient, the infant’s MRHP shall:

a) provide the names and locations of available outpatient labs (including the hospital’s outpatient lab) to the individuals, advising them of the need to travel to a lab to have the blood testing completed;

b) allow each individual to choose the most convenient lab; and

c) fax the completed Blood and Body Fluid Exposure Testing Requisition Form to the respective individual’s chosen lab.

9. Reviewing Blood Test Results and Informing Respective Parties

9.1 Refer to Appendix B: Infant Follow-Up from Blood Test Results for guidance based on positive and/or negative blood test results.

9.2 If blood testing on the source person occurred, the infant’s MRHP shall:
a) review and “match” the source person’s blood test results to the infant (if informed consent was obtained, refer to Section 6.1 b) above) for the purpose of assessing the risk of blood borne virus transmission to the infant and/or for treating the infant;

b) disclose the source person’s non-identifying blood test results, in a manner consistent with Section 3.1 above, to the infant’s guardian(s), if informed consent was obtained (refer to Section 6.1 c) above); and

c) contact the source person’s MRHP and advise of the:
   (i) breastfeeding CAE;
   (ii) completion of the AHS Source Person’s Risk of Infection Assessment Form, if applicable;
   (iii) review of the source person’s health record, if applicable;
   (iv) completion of the source person’s lab requisition; and
   (v) need for the source person’s MRHP to:
       • review the source person’s blood test results;
       • provide follow-up counselling and treatment, if applicable, to the source person; and
       • notify the MOH if any reportable blood borne viruses are identified in the source person’s blood test results, in accordance with the Public Health Act (Alberta).

9.3 If blood testing on the birth parent occurred, the infant’s MRHP shall:

a) review and “match” the birth parent’s blood test results to the infant (if informed consent was obtained, refer to Section 6.2 a) above), for the purpose of establishing a baseline for the infant and/or for treating the infant;

b) disclose the birth parent’s blood test results to the infant’s guardian(s), if informed consent was obtained from the birth parent (as per Section 6.2 b) above); and

c) contact the birth parent’s MRHP and advise of the:
   (i) breastfeeding CAE;
   (ii) completion of the birth parent’s lab requisition; and
   (iii) need for the birth parent’s MRHP to:
• review the birth parent’s blood test results;
• provide follow-up counselling and treatment, if applicable, to the birth parent; and
• notify the MOH if any reportable blood borne viruses are identified in the birth parent’s blood test results, in accordance with the Public Health Act (Alberta).

10. Treatment/Follow-up, If Required

10.1 If the source person’s, birth parent’s, and/or infant’s blood test results are positive, the infant’s MRHP shall:

a) contact a Pediatric Infectious Diseases Specialist (see Section 7.1 c above);

b) provide counselling to the infant’s guardian(s) regarding treatment for the infant, if applicable;

c) provide treatment to the infant, as appropriate, in accordance with the AHS Consent to Treatment/Procedure(s) Policy Suite; and

d) notify the MOH if any reportable blood borne viruses are identified in the infant’s blood test results, in accordance with the Public Health Act (Alberta).

10.2 If the source person’s and/or birth parent’s blood test results are positive, the infant’s MRHP shall contact the respective MRHP and shall advise them to:

a) provide counselling regarding treatment, if applicable;

b) provide or access treatment as appropriate; and

c) notify the MOH if any reportable blood borne viruses are identified in their patient’s blood test results, in accordance with the Public Health Act (Alberta).

11. Documentation by the Health Care Professional

11.1 When documenting facts related to the breastmilk CAE in either of the infant’s, birth parent’s, infant’s guardian(s), or the source person’s health records, it is important to ensure that non-identifying information is documented, in a manner consistent with Section 3.1 above, to ensure the confidentiality of all involved.

a) When documenting in the infant’s health record:

   (i) the source person shall be identified as the source person;
(ii) the infant’s guardian(s) shall be identified as the infant’s guardian(s); and

(iii) the birth parent shall be identified as the birth parent.

b) When documenting in the birth parent’s health record:

(i) the source person shall be identified as the source person;

(ii) the infant’s guardian(s), if applicable, shall be identified as the infant’s guardian(s); and

(iii) the infant shall be identified as the infant.

c) When documenting in the source person’s health record:

(i) the source person shall be identified as the source person;

(ii) the infant’s guardian(s) shall be identified as the infant’s guardian(s); and

(iii) the birth parent shall be identified as the birth parent.

11.2 Documentation in the infant’s health record, outlining the facts related to the breastmilk CAE shall include the following, as appropriate:

a) notification of the Charge Nurse, the infant’s MRHP, and the Unit Manager regarding the occurrence;

b) disclosure of the CAE provided to the infant’s guardian(s);

c) counselling provided to the infant’s guardian(s) related to the potential level of risk of transmission of blood borne viruses to the infant, including non-identifying information related to the results of the following:

(i) birth parent’s blood testing; and

(ii) source person’s:

- AHS Source Person’s Risk of Infection Assessment Form;
- health record review; and/or
- blood testing;

d) decision or refusal by the source person to complete the AHS Source Person’s Risk of Infection Assessment Form, to have their health record reviewed, if applicable, and/or blood testing;
(i) Notification of an Infectious Diseases Specialist, or others, if the source person refused the completion of any of the above, or if the source person’s blood test results are positive.

e) decision or refusal by the birth parent for blood testing;

   (i) Notification of an Infectious Diseases Specialist, or others, if the birth parent’s blood test results are positive or if the birth parent refused blood testing.

f) decision whether to blood test the infant, including the:

   (i) counselling and informed consent discussion;

   (ii) AHS Consent to Treatment Plan or Procedure Form, signed by the infant’s guardian(s), if written consent obtained; and

   (iii) completion of lab requisition and blood draw;

g) notification of the MOH if any reportable blood borne viruses are identified in the infant’s blood test results, in accordance with the Public Health Act (Alberta);

h) results of the review and “matching” of the source person’s and the birth parent’s blood test results to the infant;

i) disclosure of the source person’s and birth parent’s blood test results to the infant’s guardian(s); and

j) treatment/follow-up for the infant, as appropriate, including but not limited to the following:

   (i) contact with a Pediatric Infectious Diseases Specialist;

   (ii) counselling to the infant’s guardian(s) regarding treatment;

   (iii) informed consent discussion; and

   (iv) AHS Consent to Treatment Plan or Procedure Form, signed by the infant’s guardian(s), if written consent was obtained.

11.3 Documentation in the birth parent’s health record outlining the facts of the breastmilk CAE, shall include the following, as appropriate:

a) notification of the infant’s MRHP that a breastmilk CAE occurred;

b) disclosure of the CAE provided to the infant’s guardian(s);

c) counselling provided to the birth parent, and the infant’s guardian(s), if applicable, related to:
(i) the potential level of risk of transmission of blood borne viruses to the infant; and

(ii) the birth parent’s blood test results, being provided to the infant’s guardian(s), in a manner consistent with Section 3.1 above;

d) pre-blood test counselling to the birth parent, including the need to contact the birth parent’s MRHP to review the birth parent’s blood testing results and to provide follow-up, if required;

e) blood testing of the birth parent, if occurred, as well as the:

(i) informed consent discussion;

(ii) AHS Consent to Blood Testing for Blood Borne Viruses Form, signed by the birth parent;

(iii) AHS Consent to Disclose Health Information Form, signed by the birth parent;

(iv) time and location of the lab that the lab requisition was faxed to (if applicable); and

(v) name of the birth parent’s MRHP and when the infant’s MRHP made contact with the birth parent’s MRHP;

f) refusal of blood testing, if applicable.

Note: If the birth parent is not an inpatient, create an ambulatory health record to document this information. Contact your local Health Information Management (HIM) department to determine the process for creating a health record.

11.4 Documentation in the source person’s health record, outlining the facts of the breastmilk CAE shall include the following, as appropriate:

a) notification of the infant’s MRHP that a breastmilk CAE occurred;

b) disclosure of the CAE provided to the source person;

c) counselling to the source person related to:

(i) the potential level of risk of transmission of blood borne viruses to the infant, including non-identifying information, in a manner consistent with Section 3.1 above;

(ii) the need to obtain informed consent for the completion of the AHS Source Person’s Risk of Infection Assessment Form, review of the source person’s health record, and/or blood testing; and
(iii) the need to contact the source person’s MRHP, if blood testing occurred;

d) AHS Source Person’s Risk of Infection Assessment Form, if applicable, including the:
   (i) informed consent discussion;
   (ii) contact with Pediatric Infectious Diseases Specialists or other Specialists, if required; and
   (iii) AHS Consent to Disclose Health Information Form, signed by the source person, if written informed consent was obtained;

e) review of the source person’s health record, if occurred, as well as the:
   (i) informed consent discussion; and
   (ii) AHS Consent to Disclose Health Information Form, signed by the source person;

f) blood testing of the source person, if occurred, as well as the:
   (i) pre-blood test counselling, including the informed consent discussion;
   (ii) AHS Consent to Blood Testing for Blood-Borne Viruses Form, signed by the source person;
   (iii) time and location of the lab that the lab requisition was faxed to (if applicable); and
   (iv) name of the source person’s MRHP and when contact was made by the infant’s MRHP;

g) refusal of the AHS Source Person’s Risk of Infection Assessment Form, review of the source person’s health record, and/or blood testing, if applicable.

Note: If the source person is not an inpatient, create an ambulatory health record to document this information. Contact your local HIM department to determine the process for creating a health record.

11.5 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 breastmilk related CAEs and close calls.
DEFINITIONS

Birth parent means the individual who gave birth to the infant and produces breastmilk that is given to the 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.

Clinical leader means the senior leader immediately available to provide immediate management of a clinical adverse event. This may be a charge nurse, on-duty supervisor, administrator on call, most responsible health practitioner, unit manager or other leader as appropriate.

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.

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.
**Inpatient** means a patient admitted to and staying in an Alberta designated hospital, or other approved facility, where goods or services are delivered by, on behalf of or in conjunction with Alberta Health Services.

**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.

**Outpatient** means a patient staying at home or in another facility that is not a designated hospital in Alberta, or who is accepted as a registered patient for goods or services offered or delivered by, on behalf of or in conjunction with Alberta Health Services, but who returns to their normal abode after the good or service is rendered or delivered.

**Patient** means all persons, inclusive of residents and clients, who received or have requested health care or services from Alberta Health Services and its health care providers. Patient also means, where applicable:

a) a co-decision-maker with the person; or

b) an alternate decision-maker on behalf of the person.

**Source person** means the individual who is the source of the incorrect breastmilk.

**REFERENCES**

- Appendix A: *When an Infant Unintentionally Receives Incorrect Breastmilk Flowchart*
- Appendix B: *Infant Follow-Up from Blood Test Results*
- Alberta Health Services Governance Documents:
  - *Breastmilk Safe Management Policy* (#PS-16)
  - *Breastmilk Safe Management Procedure* (#PS-16-01)
  - *Collection, Access, Use, and Disclosure of Information Policy* (#1112)
  - *Consent to Treatment/Procedure(s) Policy Suite* (#PRR-01)
  - *Pasteurized Donor Human Milk Procedure* (#HCS-294-01)
  - *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy Suite* (#PS-95)
- Alberta Health Services Forms:
  - *Blood and Body Fluid Exposure Testing Requisition Form* (Alberta Provincial Laboratory for Public Health) (#21150)
  - *Consent to Blood Testing for Blood Borne Viruses Form* (#18213)
  - *Consent to Disclose Health Information Form* (#18028)
  - *Consent to Treatment Plan or Procedure Form* (#09741)
  - *Source Person’s Risk of Infection Assessment (When an Infant Unintentionally Receives Incorrect Breastmilk)* Form (#21374)
- Alberta Health Services Resources:
  - *Checklist - Breastmilk Safe Management: When an Infant Unintentionally Receives Incorrect Breastmilk*
  - *Patient Information Sheet – Blood Borne Virus Testing*
• Non-Alberta Health Services Documents:
  o Adult Guardianship and Trusteeship Act (Alberta)
  o Child, Youth and Family Enhancement Act (Alberta)
  o Family Law Act (Alberta)
  o Health Information Act (Alberta)
  o Health Professions Act (Alberta)
  o Public Health Act (Alberta)
  o Standard of Practice Continuity of Care (College of Physicians and Surgeons of Alberta)
When an Infant Unintentionally Receives Incorrect Breastmilk Flowchart

1. **Health Care Professional**
   - **Infant Receives Incorrect Breastmilk**
   - Notify Charge Nurse of breastmilk clinical adverse event (CAE)
   - Document CAE in infant's health record
   - Document applicable steps in RLS

2. **Charge Nurse**
   - Notify infant's MRHP of CAE
   - Document notification in source person's, birth parent's, and infant's health records
   - Notify Unit Manager of CAE
   - Document notification in infant's health records

3. **Infant's MRHP**
   - Provide counselling related to the risk of infection assessment, health record review, and blood testing
   - Consents to assessment, review of health record, &/or blood testing, and disclosure of information?
     - Yes
     - Yes: Perform the Risk of Infection Assessment Form &/or review health record
     - Yes: Complete Provincial Lab Requisition for blood testing & request copy of results to source person's MRHP
     - Yes: Match blood testing results to infant, to determine risk
     - Yes: Notify source person's MRHP of CAE and request follow-up
     - Yes: Document all applicable steps in source person's and infant's health records, and RLS
     - No: Consult a Pediatric Infectious Diseases Specialist
   - No
     - No: Birth parent consents to blood testing & disclosure of information?
       - Yes
       - Yes: Complete Provincial Lab Requisition for infant blood testing
       - Yes: Match blood testing results to the infant to determine risk
       - Yes: Notify birth parent's MRHP of CAE and request follow-up
       - Yes: Obtain infant's blood testing results
       - Yes: Document all applicable steps in infant's health records
       - No: Consult a Pediatric Infectious Diseases Specialist
       - No: Guardian(s) consent to infant's blood testing?
         - Yes
         - Yes: Complete Provincial Lab Requisition for infant blood testing
         - Yes: Obtain infant's blood testing results
         - Yes: Document all applicable steps in infant's health records
         - No: Consult a Pediatric Infectious Diseases Specialist
         - No: Not treatment OR If either source person or birth parent is considered high risk, consult a Pediatric Infectious Diseases Specialist, for potential repeat blood work in three months
     - No
       - No: Notify guardian(s) of results
       - No: Positive Result
       - No: Negative Result

4. **Birth Parent and Guardian (s) of Infant**
   - Match blood testing results to the infant to determine risk
   - Notify birth parent's MRHP of CAE and request follow-up
   - Document all applicable steps in source person's and infant's health records, and RLS

5. **Source Person’s MRHP and Birth Parent’s MRHP**
   - Each MRHP obtains and reviews the respective blood testing results, if applicable
   - Each MRHP counsels their respective “patient” regarding their blood testing results & any follow-up, if applicable
   - Each MRHP documents the blood testing results, counselling, and follow-up, if applicable, in the respective health records

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APPENDIX B

Infant Follow-Up from Blood Test Results

If the source person, the birth parent, or the infant tests positive to any of the blood tests identified in the table below, the infant’s MRHP shall complete the identified “Follow-Up Action for the Infant”;

Or

If the source person, the birth parent, or the infant tests negative to any of the blood tests, no further action or follow-up is required for the infant.

Note: If either the source person or the birth parent tests negative and is considered high risk (e.g., a sex worker or uses injection drugs), consult a Pediatric Infectious Diseases Specialist, as follow-up blood testing may be indicated in three (3) months (as the individual may be in the incubation period for a blood borne virus).

<table>
<thead>
<tr>
<th>Blood Test</th>
<th>Follow-Up Action for the Infant</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV antibodies</td>
<td>• Immediately consult a Pediatric Infectious Diseases Specialist regarding possible antiviral chemoprophylaxis and follow-up blood test for the infant.</td>
</tr>
<tr>
<td>Hepatitis B surface antigen (HBsAg)</td>
<td>• Consult a Pediatric Infectious Diseases Specialist.</td>
</tr>
<tr>
<td></td>
<td>• Confirm the infant has received the HBV vaccine and HBIG at delivery; otherwise, offer the HBV vaccine and HBIG to the infant.</td>
</tr>
<tr>
<td>Hepatitis C (HCV) antibodies</td>
<td>• Consult a Pediatric Infectious Diseases Specialist.</td>
</tr>
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<td></td>
<td>• HCV status for the infant can be determined by blood testing for HCV antibodies at 18 month of age, with consideration for an early screen using HCV PCR at 3 months of age.</td>
</tr>
<tr>
<td>CMV IgG</td>
<td>• Decision of whether to blood test the infant for CMV infection requires discussion between the infant’s MRHP and a Pediatric Infectious Diseases Specialist.</td>
</tr>
<tr>
<td></td>
<td>• Discuss potential symptomatic clinical illness if infant was born at less than 34-week gestation and/or less than 1500 grams birth weight.</td>
</tr>
<tr>
<td>HTLV-1 and HTLV-II antibodies</td>
<td>• Decision of whether to blood test the infant requires discussion between the infant’s MRHP and a Pediatric Infectious Diseases Specialist.</td>
</tr>
</tbody>
</table>