

TITLE

EXPRESSED BREAST MILK: WHEN MILK IS GIVEN TO AN UNINTENDED INFANTDOCUMENT #
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If you have any questions or comments regarding the information in this procedure, please contact the Clinical Policy Department at clinicalpolicy@albertahealthservices.ca. The Clinical Policy website is the official source of current approved clinical policies, procedures and directives.

OBJECTIVES

- The purpose of this procedure is to outline the steps to be taken when an infant receives another mother's expressed breast milk unintentionally.

APPLICABILITY

Compliance with this procedure 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 services providers as necessary). This procedure does not limit any legal rights to which you may otherwise be entitled.

PROCEDURE**1. Notification and Disclosure**

- 1.1 Upon realizing that an infant has received expressed breast milk from an unintended **source mother**, the **health care professional** shall immediately notify the charge nurse and the infant's **most responsible health practitioner**.
- 1.2 In the case of an expressed breast milk 'near miss' or 'close call' with potential for errors or mix-ups, this event should be reported to the charge nurse with

discussion regarding the submission of a report in the Reporting Learning System (RLS).

- 1.3 Disclosure and counseling will be offered to the source mother, the infant's **parent/guardian(s)** and the staff member(s) involved in accordance with the *Disclosure of Harm* policy. Responsibility for disclosure and counseling is decided by the infant's most responsible health practitioner or designate based on the presenting situation and conditions. Guidelines for disclosure can be found in Alberta Health Services *Disclosure of Harm Policy* PS-01 and Alberta Health Services *Disclosure of Harm Procedure* PS-01-01.
- 1.4 Additional resources are available in the Alberta Health Services *Expressed Breast Milk Staff and Physician Information Package*, which includes:
- a) *Expressed Breast Milk Reportable Event Staff/Physician Checklist* (Appendix A);
 - b) *Expressed Breast Milk Reportable Event Risk Assessment Form* (Appendix B); and
 - c) *Expressed Breast Milk Reportable Event Risk Assessment Results Checklist* (Appendix C).

The infant's most responsible health practitioner may consult a variety of resources to assist in the risk assessment process. These resources may include but are not limited to Infectious Disease practitioners, Neonatal/Pediatric Specialists, the Medical Officer of Health and or Infection Protection Control practitioners based on need and availability.

To contact Pediatric Infectious Disease Specialist located in:

- Calgary**, please call Alberta Children's Hospital Switchboard **(403-955-7211)**,
- Edmonton**, please call Stollery Children's Hospital Switchboard **(780-407-8822)**.

- 1.5 The infant's most responsible health practitioner is responsible to explain and offer the source mother a risk assessment.
- 1.6 Counseling to the source mother and the infant's parent/guardian includes providing information regarding:
- a) risks of viral transmission from expressed breast milk; and
 - b) rationale for blood work.
- 1.7 If the source mother is known to be infected with a blood borne virus or is determined to be high risk based on the risk assessment, the infant's most responsible health practitioner shall make referrals to the source mother's most responsible health practitioner as required.

2. Blood Testing

- 2.1 The infant's most responsible health practitioner or delegate arranges to offer and obtain consent for testing, utilizing a stepwise approach as summarized in Appendix C *Expressed Breast Milk Reportable Event Risk Assessment Checklist*.
- 2.2 Testing is required for the:
- infant;
 - infant's mother; and
 - source mother.
- 2.3 Testing will include:
- HIV;
 - Hepatitis B;
 - Hepatitis C;
 - CMV where the infant is less than 34 weeks gestation and/or less than 1500 grams birth weight; and
 - HTLV-I and HTLV II antibodies if source mother is from an endemic area (Japan, Caribbean countries, sub-Saharan Africa, and Nunavut).

STAT Provincial Laboratory Requisitions shall be completed for this blood work.

- 2.4 Each individual has the right to receive pre-test counseling. The infant's most responsible practitioner or designate shall make arrangements to provide counseling for each mother involved.
- Counseling for the source mother should include:
 - The need to obtain the source mother's formal consent for blood testing;
 - The identity of the source mother will **not** be shared with the infant's parent/guardian; only the risk of infection to the infant based on the source mother's test result findings;
 - Should blood testing identify any reportable infections/diseases, Infection Prevention & Control and Communicable Disease will be notified in accordance with the Alberta *Public Health Act* Section 22.
 - Counseling for the infant's family should include:

- The potential risk of transmission of an infectious disease as identified from the risk assessment;
 - Should blood testing identify any reportable infections/diseases, Infection Prevention & Control and/or Communicable Disease will be notified in accordance with the Alberta *Public Health Act* Section 22; and
 - Follow-up testing for both infant and infant's mother could be required depending on the test results of the source mother.
- 2.5 If the source mother refuses to be tested then the infant's parent/guardian(s) should be informed and the infant is to be tested.
- 2.6 If the source mother is not an admitted **patient** she must go to an **outpatient** lab for blood testing.
- 2.7 The infant's most responsible health practitioner shall be responsible for ordering all blood work on all parties involved. The name(s) of the most responsible health practitioner for both the source mother and the infant's mother shall be included on the respective laboratory requisitions to ensure appropriate notification of each individual's most responsible health practitioner.
- 2.8 The infant's most responsible health practitioner is expected to inform the infant's parent/guardian(s) of the infant's blood results.
- a) The source mother's identifiers will be protected from disclosure to the infant's parent/guardian in compliance with the *Health Information Act* and the *Public Health Act*.
 - b) The infant's most responsible health practitioner is responsible for "matching" the laboratory test results of the source mother to the infant for the purposes of confirming the risk of infectious disease transmission to the infant and initiating appropriate follow-up if required.
- 2.9 The most responsible health practitioners for the source mother and the infant's mother are expected to inform their respective patients of the blood results and initiate appropriate follow-up if required.
- 3. Follow-Up Support**
- 3.1 The infant's parent/guardian(s) should be advised of the options for follow-up and follow-up should be arranged as appropriate. (Refer to the Alberta Health Services *Staff and Physician Information Package*).
- 4. Documentation**
- 4.1 Document the incident, procedures and processes in the infant's **health record**. Do not include any identifying information of the source mother.

- 4.2 Document the parent/guardian education and counseling provided and any follow-up that has been arranged.
- 4.3 The source mother's *Risk Assessment Form* is placed in her health record. The infant's most responsible health practitioner makes a notation in the infant's health record with respect to the level of risk of transmission to the infant.
- 4.4 The appropriate health care professional will submit a report in the Reporting Learning System (RLS).

DEFINITIONS

Guardian means where applicable

For a minor:

- a) as defined in the *Family Law Act*;
- b) as per agreement or appointment authorized by legislation (obtain copy of the agreement and verify it qualifies under legislation; e.g., agreement between the Director of Child and Family Services Authority and foster parent(s) under the *Child, Youth and Family Enhancement Act*, or agreement between parents under the *Family Law Act*, or as set out in the *Child, Youth and Family Enhancement Act* regarding Guardians of the child to be adopted once the designated form is signed);
- c) as appointed under a will (obtain a copy of the will; also obtain grant of probate, if possible);
- d) as appointed in accordance with a personal directive (obtain copy of personal directive);
- e) as appointed by court order (obtain copy of court order) (e.g., order according to the *Child, Youth and Family Enhancement Act*.); and,
- f) a divorced parent who has custody of the minor.

Health care professional means an individual who is a member of a regulated health discipline, as defined by the *Health Disciplines Act* or the *Health Professions Act*, and who practises within scope or role.

Health record means the Alberta Health Services legal record of the patient's diagnostic, treatment and care information.

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

Parent means the adult guardian of a child in accordance with the Alberta Family Law Act (see Appendix D – *Overview of the Definition of “Guardian” as set out in Section 20 of The Family Law Act*).

Patient means all persons who receive or have requested health care or services from Alberta Health Services and its health care providers and also means, where applicable:

- a) a co-decision-maker with the person; or
- b) an alternate decision-maker on behalf of the person.

Source mother means the mother whose Expressed Breast Milk was unintentionally given to an infant other than her own.

REFERENCES

- Appendix A Expressed Breast Milk Reportable Event Risk Checklist
- Appendix B Expressed Breast Milk Reportable Event Risk Assessment Form
- Appendix C Expressed Breast Milk Reportable Event Risk Assessment Checklist
- Alberta Health Services, Disclosure of Harm Policy PS-01
- Alberta Health Services Disclosure of Harm Procedure PS-01-01
- Alberta Health Services, Consent Policy & Procedures PRR-01
- Public Health Act (Alberta)

REVISIONS

N/A

APPENDIX A

Expressed Breast Milk Reportable Event Staff/Physician Checklist

The following process must be initiated in the event that an infant receives Expressed Breast Milk (EBM) from a source mother. This incident is considered an adverse event. Although there may be no evidence of apparent harm at the time of the event or reporting of the event, the infant may experience harm in the future.

Steps	Actions	Responsible Professional	Complete Date/Time	Staff Initials
#1	Health care professional notifies the charge nurse. Charge nurse notifies the infant's most responsible health practitioner.	Health care professional		
#2	Inform both the source mother and the infant's mother of the incident as per the Alberta Health Services Policy <i>Safe Disclosure</i> (#EC-01) and maintain confidentiality. Provide initial counseling and information and document the discussions	Most responsible health practitioner (infant)		
#3	Perform a risk assessment of the source mother utilizing the <i>Risk Assessment Form</i> , documenting findings on the form and health record. The <i>Risk Assessment Form</i> becomes a part of the source mother's health record.	Most responsible health practitioner (infant)		
#4	If the source mother refuses to be tested then the infant's parent/guardian(s) should be informed and the infant is to be offered to be tested.	Most responsible health practitioner (infant)		
#5	Determine the level of risk to the infant based on the <i>Risk Assessment Form</i> and other relevant factors.	Most responsible health practitioner (infant)		
#6	Provide pre-blood work counseling, and obtain the source mother's: a) written consent for the required lab work; b) verbal consent to access her charts as required; and c) verbal consent to disclose the results of the risk assessment (no names) to the infant's parent/guardian(s). Document all discussions.	Most responsible health practitioner (infant)		

#7	<p>Complete a STAT Provincial Laboratory Requisition for the following Blood Testing:</p> <ul style="list-style-type: none"> •HIV; •Hepatitis B surface antigen (HBsAg); •Hepatitis C (HCV) antibodies; •CMV IgG where the infant is < 34 weeks gestation and/or < 1500 g birth weight; and •HTLV-I and HTLV II antibodies if source mother is from an endemic area (Japan, Caribbean countries, sub-Saharan Africa, and Nunavut). <p>Include the name of the infant's most responsible health practitioner on the requisition.</p> <p>Give requisition to the source mother.</p>	Most responsible health practitioner (infant)		
#8	Provide pre-blood work counseling to the infant's family/guardian, and obtain written consent for blood testing of the infant.	Most responsible health practitioner (infant)		
#9	Offer blood-work testing to the infant's mother.	Most responsible health practitioner (infant)		
#10	<p>Complete STAT Provincial Laboratory Requisitions for the infant and the infant's mother if accepted.</p> <p>Blood Testing to include:</p> <ul style="list-style-type: none"> • HIV; • Hepatitis B surface antigen (HBsAg); • Hepatitis C (HCV) antibodies; • CMV IgG where the infant is < 34 weeks gestation and/or < 1500 g birth weight; and • HTLV-I and HTLV II antibodies if source mother is from an endemic area (Japan, Caribbean countries, sub-Saharan Africa, and Nunavut). <p>Include the name of the infant's most responsible health practitioner on the infant's mother's requisition if the infant's mother agreed to testing</p>	Most responsible health practitioner (infant)		
#11	<p>Review blood testing results from all sources.</p> <p>Initiate contact with most responsible health practitioners for the source mother and/or the infant's mother as appropriate based on blood testing results.</p>	Most responsible health practitioner (infant)		

#12	<p>Notify infant's family of blood testing results, provide education and counseling regarding next steps and follow-up as appropriate, refer infant to Pediatric Infectious Disease Specialist.</p> <p>To contact Pediatric Infectious Disease Specialist located in :</p> <ul style="list-style-type: none"> •Calgary, please call Alberta Children's Hospital Switchboard (403-955-7211) •Edmonton, please call Stollery Children's Hospital Switchboard (780-407-8822) <p>Document all education, counseling and referrals on the infant's health record.</p>	Most responsible health practitioner (infant)		
#13	Complete a Report & Learning System (RLS) Report; forward copy to Unit Manager and Infection Prevention & Control for surveillance data collection.	Health care professional / most responsible health practitioner (infant)		

Staff Name / initials _____ Practitioner Name / Initials _____

Information to Consider: Viruses that may be Transmitted by Expressed Breast Milk (EBM)

Overall, the risk of viral transmission by an isolated inadvertent ingestion of EBM is suspected to be extremely low. There are several viruses that may be transmitted by breast milk. These include:

- Human Immunodeficiency Virus (HIV),
- Cytomegalovirus (CMV),
- Human T-cell Lymphotropic Virus-1 (HTLV-1), and
- Human T-cell Lymphotropic virus-2 (HTLV-2).

Other viruses such as Hepatitis B and Hepatitis C are transmitted primarily by blood, and have been found in breast milk of infected mothers.

Viral Information

HIV

There have been no reports in the medical literature of any cases of HIV transmission through EBM fed to an unintended infant. The risk of HIV transmission via EBM ingested accidentally is very low. When an infant is fed milk from a mother who has HIV infection, there is a low probability that the infection will be passed to the infant. The risk may be higher when an HIV positive mother is not on treatment or has a high viral load. The risk will also depend on the quantity of EBM that has been consumed. If a mother is confirmed to be HIV positive in Canada, breastfeeding and expressing breast milk for the purpose of infant feeding is contraindicated. If a baby is fed breast milk from an HIV positive mother, an infectious diseases physician can help determine if antiretroviral medications are required for the baby.

CMV

CMV transmission can occur via EBM. Full term infants exposed to CMV in EBM usually have no symptoms or sequelae. Premature infants (less than 34 weeks gestational age) or low birth weight infants (less than 1500 grams) may develop illness if exposed to EBM that is infected with CMV. Overall, the vast majority of babies infected with CMV are asymptomatic and do not require treatment. Treatment is reserved for a very small minority of babies who have severe disease. No specific prophylaxis is available to help prevent infection with CMV. If the baby is premature or low birth weight as defined above, then an infectious diseases physician can help determine if any treatment is required for the baby.

HTLV-1 and HTLV-2

HTLV-1/2 can be transmitted via EBM. However, these viruses are thought to be rare in North America. There is no specific treatment for these viruses at this time and the consequences of infection are not completely clear. If a mother is found to be infected with either of these viruses in Canada, breastfeeding and expressing breast milk for the purpose of infant feeding are contraindicated. No specific prophylaxis is available to help prevent infection with HTLV-1/2 if a baby is exposed.

Hepatitis B and Hepatitis C

Both Hepatitis B and Hepatitis C have been found in breast milk but are not thought to be transmitted via breast milk. The main route of transmission for these viruses is through blood. If a mother is found to be infected with either of these viruses she may breastfeed normally. However, for babies that receive breast milk from a mother infected with Hepatitis B (HBsAg positive) prophylaxis in the form of Hepatitis B immune globulin and Hepatitis B vaccine can be given to the baby.

APPENDIX B

Expressed Breast Milk Reportable Event Risk Assessment Form

Risk factor information on the source mother is required to assist in the assessment of risk(s) to the infant that has received the source mother's Expressed Breast Milk (EBM). Source mothers are requested to answer Yes or No to the following questions:

General Risk:

1. Are you currently taking any prescription medications, herbal remedies or nutritional supplements? Yes No Decline
2. Have you accepted money or drugs in exchange for sex? Yes No Decline
3. Have you ever used intravenous illegal street drugs? Yes No Decline
4. Have you had a sexual partner who has participated in high risk activities such as men who have sex with men, accepted money or drugs in exchange for sex, used intravenous illegal street drugs or unknown sexual background? Yes No Decline

If the source mother answers **Yes** to any of the above questions the source mother is considered high risk for HIV infection. The next steps are:

- Notify the appropriate Infectious Disease Department.
- Obtain written consent for STAT blood testing of the source mother.
- Complete a Provincial Laboratory Requisition for :
 - o HIV
 - o Hepatitis B
 - o Hepatitis C
 - o CMV where the infant is less than 34 weeks gestation or less than 1500 grams birth weight
 - o HTLV-I and HTLV II antibodies if source mother is from an endemic area (Japan, Caribbean countries, sub-Saharan Africa, and Nunavut).

Consent for blood work obtained: Yes No Declined

Physician/Designate (Print name/Signature) Date and Time

Reference: Canadian Blood Services (September, 2010). Record of Donation. Ottawa: Author

APPENDIX C

Expressed Breast Milk Reportable Event Risk Assessment Results Checklist

Baseline	Follow-Up Action
<p>Fill out the <i>Risk Assessment Form</i> for the source mother.</p> <p>Obtain source mother's consent for these blood tests:</p> <ul style="list-style-type: none"> •HIV antibodies; •Hepatitis B surface antigen (HBsAg); •HCV antibodies; •CMV IgG; and •HTLV-I/II antibodies if mother is from endemic areas (Japan, Caribbean countries, sub-Saharan Africa, and Nunavut). 	<p>If there are significant risk factors for the blood-borne pathogen infection for the source mother, please consult with Pediatric Infectious Disease Specialists at the Stollery Children's Hospital (Edmonton) and the Alberta Children's Hospital (Calgary).</p> <p>If there is no significant behavioural risk for blood-borne pathogen infection for the source mother and all the baseline tests of the source mother are negative, no further testing is required.</p>
<p>Blood Test Results Obtained:</p> <p>Initiate Follow-Up Actions as outlined below for the specific test result:</p>	
<p>HIV antibodies</p>	<p>Consult Pediatric Infectious Disease Specialist regarding possible antiviral chemoprophylaxis and follow-up test for infant immediately.</p> <p>Obtain HIV antibodies test for the recipient infant's mother as baseline.</p>
<p>HBsAg</p>	<p>Review recipient infant's mother hepatitis B status:</p> <p>If recipient infant's mother is positive for HBsAg, confirm that infant has received HBV vaccine and HBIG at delivery, otherwise offer vaccine and HBIG to infant. Follow-up as per protocol for infants born to HBsAg positive mothers (HBsAg and Anti-HBs at 1 month following and within 6 months of completion of HBV vaccine series). Counsel regarding exposure risk and potential outcome.</p> <p>If recipient infant's mother is negative for HBsAg and recipient infant has not received HBV vaccine and HBIG, do HBsAg and Anti-HBs testing on recipient infant's mother. Provide HBV vaccine and HBIG to recipient infant. Follow-up for the infant: HBsAg and Anti-HBs at 1 month following and within 6 months of completion of HBV vaccine series.</p>

	<p>Counsel regarding exposure risk and potential outcome.</p>
HCV antibodies	<p>Obtain HCV antibodies test for the recipient infant's mother as baseline.</p> <p>If recipient infant's mother tested positive for HCV antibodies, HCV status for the infant can be determined by testing for HCV antibodies at 18 month of age with consideration for an early screen using HCV PCR at 3 months of age.</p> <p>Counsel regarding exposure risk and potential outcome.</p> <p>If recipient infant's mother tested negative for HCV antibodies, follow-up with HCV antibodies testing for infant at 3 and 6 months post- exposure.</p> <p>Counsel regarding exposure risk and potential outcome.</p>
CMV IgG	<p>Obtain CMV antibodies test for the recipient infant's mother as baseline.</p> <p>If recipient infant's mother tested positive for CMV IgG, it is not possible to differentiate source of infection if infant is infected.</p> <p>Counsel regarding exposure risk and potential outcome.</p> <p>If recipient infant's mother tested negative for CMV IgG, counsel regarding exposure risk and potential outcome.</p> <p>Discuss potential symptomatic clinical illness if infant was born at less than 34-week gestation and/or less than 1500 grams birth weight, and consider baseline urine for CMV and follow-up testing at 1 and 3 months.</p>
HTLV I/II antibodies	<p>Obtain HTLV I/II antibodies test for the recipient infant's mother as baseline and counsel regarding exposure risk and potential outcome.</p> <p>If recipient infant's mother tested positive for HTLV I/II antibodies, it is not possible to differentiate source of infection if infant is infected.</p> <p>Counsel regarding exposure risk and potential</p>

	<p>outcome.</p> <p>If recipient infant's mother tested negative for HTLV I/II antibodies, follow-up HTLV I/II antibodies for infant at 3 and 6 month post- exposure.</p> <p>Counsel regarding exposure risk and potential outcome.</p>
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APPENDIX D

Overview of the Definition of “Guardian” as Set Out in Section 20 of the Family Law Act

A guardian is a parent if:

1. The parent has acknowledged that he or she is the parent of the child; AND
2. Has demonstrated an intention (*see guidelines below*) to assume the responsibility of a guardian in respect of the child within one year of either becoming aware of the pregnancy or becoming aware of the birth.

Parentage (who is a parent):

There are three combinations of parent-child relationships recognized under the *Family Law Act*:

Children conceived without assisted reproduction:	Children conceived with assisted reproduction and whose birth mother is the intended parent:	Children who were conceived with assisted reproduction and whose birth mother is a surrogate:
<p>Birth mother and biological father are the parents, except in the case of adoption where one would refer to the adoption Court Order. If adoption is in progress, contact Clinical Legal Services.</p> <p><i>*see below for who is presumed to be the biological father.</i></p>	<p>The birth mother will be considered to be one parent.</p>	<p>Until there is a Court Order declaring parentage, the surrogate remains the only legal parent.</p>
	<p>The other parent will depend on how the embryo was created:</p> <ol style="list-style-type: none"> 1. If the embryo was created from the intended male parent’s sperm, then the other legal parent is the intended male parent. 2. If the embryo was created from donated sperm, then 	<p>Once the surrogate has relinquished her parental rights, a Court Order will declare the proper legal parents.</p>

	the person who was married to or in a conjugal relationship with the birth mother AND consented to be a parent at the time of conception is the other parent.	
If there is a dispute over parentage, a court order may be sought to declare that someone is or is not a parent of a particular child. For Adoptions, a Court Order will be provided.		

INTENTION***May be shown by any of the following:***

1. Being married to the other parent at the time of the birth of the child;
2. Being married to the other parent after the birth of the child;
3. Being married to the other parent that, within 300 days before the birth of the child ended by death, decree of nullity or judgment of divorce;
4. Being an adult Interdependent partner of the other parent at the time of birth of the child;
5. Being an adult Interdependent partner with the other parent after the birth of the child;
6. Having cohabitated with the other parent for at least 12 consecutive months during which time the child was born;
7. Having entered into an agreement with the other parent to be a guardian under the *Family Law Act*;
8. Having carried the pregnancy to term (for the birth mother);
9. Where the other Parent is the birth mother, voluntarily providing or offering to provide support for the birth mother during or after her pregnancy, not by court order;
10. Voluntarily providing or offering to provide reasonable direct or indirect financial support for the child;
11. Court Order (Court may find other evidence to be that of Intention);
12. Where the child is born as a result of assisted reproduction, being a Parent of the child under section 8.1 (see middle column under Parentage above).

BIOLOGICAL FATHER***The following will be presumed to be the biological father where the child was born without assisted reproduction (see first column under Parentage above):*****The male person who:**

1. Was married to the birth mother at the time of the child's birth;
2. Was married to the birth mother by a marriage that within 300 days before the birth of the child ended by: death; decree of nullity; or judgment of divorce;
3. Married to the birth mother after the child's birth and has acknowledged that he is the father;
4. Cohabitated with the birth mother for at least 12 consecutive months during which time the child was born and he has acknowledged that he is the father;
5. Cohabitated with the birth mother for at least 12 consecutive months and the period of cohabitation ended less than 300 days before the birth of the child;
6. Is registered as the parent of the child at the joint request of himself and the birth mother under the *Vital Statistics Act*, or under similar legislation in a province or territory other than Alberta;
7. Has been found by a court of competent jurisdiction in Canada to be the father of the child for any purpose.

Note: Two people *cannot* be presumed to be the biological father. If that is the case, then no one will be presumed to be the biological father.