Quality and Safety: HMBANA Standards

HMBANA’s Standards Committee is closely monitoring the evolving situation regarding the outbreak of monkeypox and how it relates to milk banking.

Numerous safeguards are in place to protect the quality and integrity of every bottle processed, including strict donor screening, validated pasteurization, and third-party microbiological testing. One small non-peer reviewed research study indicates that heating culture plates of monkeypox virus to 60°C for 15 minutes inactivated the two identified African strains of monkeypox. Further research using milk bank procedures is needed to confirm that the virus can be eradicated using Holder Pasteurization.

HMBANA remains dedicated to providing safe donor human milk to infants in need. Screening criteria for milk donors are rigorous to protect the incoming milk supply.

Transmission and Human Milk

“Monkeypox virus can be transmitted to the fetus during pregnancy or to the newborn by close contact during and after birth.” (CDC, 2022) Therefore, direct breastfeeding, use of breastmilk, or donating milk during monkeypox infection should be delayed until criteria for discontinuing isolation have been met (all lesions have resolved and scabs have fallen off, and a new layer of intact skin has formed).

It is unknown if the monkeypox virus is transmitted in breast milk. If a lactating woman is diagnosed with monkeypox direct breastfeeding, use of breast milk, or donating milk is contraindicated, but she should be supported to continue her supply through pumping and discarding the milk. Milk donors should not donate expressed milk until criteria for discontinuing isolation have been met. It is important to know that the CDC believes that the illness cannot be transmitted without symptoms.
Screening Milk Donors

The following questions must be immediately incorporated into screening and wellness checks of all milk applicants and approved milk donors:

Exposure

Question: Have you been exposed to monkeypox?

Rationale: Exposure could be to a confirmed case of the virus, or to a symptomatic person who is waiting for a definitive diagnosis. If the answer is yes, abstain from donating for 21 days from the last day of exposure. A work exposure may be just one day, a household exposure may be much longer if multiple family members are infected. If donor does not develop monkeypox she can resume donating milk and donate milk from the full period of temporary deferral, provided she did not receive the vaccine after exposure. Exposed persons may be offered the vaccine – see deferral period below.

Symptoms/Diagnosis

Question: Do you have symptoms of monkeypox?

Rationale: Symptoms, or a diagnosis, requires deferral of milk for three days before the onset of symptoms, plus the period of active infection, plus 42 days after all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed. Milk from this time should be excluded from donation.

Treatment

Question: Have you been treated for monkeypox?

Rationale: Diagnosed individuals could receive an antiviral medication, a vaccine, and/or VIGIV. All diagnosed individuals need to refrain from donating during the active infection PLUS 42 days, regardless of treatment.

Applicants or approved donors who receive the antiviral, Tecovirimat (TPOXX or ST-246), should be deferred for 5 days (five times the half-life of 20 hours) for the medication but also must be deferred for the 21 or 42 days as appropriate (exposure vs diagnosis).

Applicants or approved donors who receive the vaccine Jynneos SHOULD be okay, but we don’t yet know. There is no data on safety of this vaccine in milk, but it is replication-deficient, largely protein-bound, and therefore unlikely to pose a risk. Until more information is known, assume the vaccine was given because of exposure and wait 21 days after receipt.

Applicants or approved donors who receive Vaccina Immune Globulin Intravenous (VIVIG) are safe to continue breastfeeding, and therefore, have no deferral from donation.
Monkeypox Deferral for Donor Infection

3 days before 1st day of symptoms 1st day of symptoms Last pox has healed 42 days after last pox has healed

(-) 3 days Active infection (+) 42 days

DONOR DEFERRAL: DO NOT USE MILK

Monkeypox Temporary Deferral for Exposure

Exposure period Quarantine period

First exposure date Last exposure date 21 days after last exposure

First and last dates of exposure (+) 21 days

TEMPORARY DONOR DEFERRAL: May use milk from temporary deferral period if donor does not develop monkeypox infection.