Imported food risk advice

Rubella virus in human milk and human milk products

Context of this risk advice

- Human milk means expressed milk collected from lactating women to be fed to infants that are not the biological infants of the women supplying the milk.
- Human milk products means products derived from human milk that have been specially formulated to meet the specific nutritional needs of infants such as fortifiers and formula.
- The level of risk for this hazard in human milk and human milk products was determined assuming that the most vulnerable category of infants (preterm infants in hospital neonatal intensive care units) would be receiving the products.

Nature of the hazard

Rubella virus (rubella) belongs to the *Togaviridae* family of viruses. It is an enveloped virus with an RNA genome and is spherical in appearance. Rubella is sensitive to heat, formaldehyde and ultraviolet light (Hobman 2013; Kuhn 2013). Like all viruses, rubella can multiply in living host cells but cannot replicate in food (Codex 2012). In postnatally infected infants rubella can be asymptomatic or potentially cause disease of mild severity.

As many countries include rubella vaccines in their national immunisation programs, many women are already immune to rubella (WHO 2018). However, women that are not vaccinated and do not have immunity from a prior infection are susceptible to rubella infection.

Transmission

Rubella is generally transmitted between humans by respiratory secretions when an infected person coughs or sneezes. Mother-to-infant transmission can occur, but predominately occurs *in utero* (ATAGI 2018; CDC 2017). A case report by Klein et al. (1980) documented a mother naturally infected with rubella eight days postpartum. The virus was shed in her milk and her infant subsequently became asymptomatically infected, implying transmission via human milk. However other routes of transmission, such as respiratory secretions were not excluded (Stiehm and Keller 2001). Vaccine strains of rubella have been demonstrated to be transmitted via human milk (Losonsky et al. 1982; Stiehm and Keller 2001), implying that wild-type rubella strains could also be transmitted via human milk.

Disease severity

In children infected postnatally, rubella usually causes mild self-limiting disease, with few noticeable symptoms. It can be asymptomatic in up to 50% of cases. In children with symptoms, these symptoms can include maculopapular rash[1], enlarged lymph nodes, low grade fever, headache, conjunctivitis, cough and runny nose (ATAGI 2018; CDC 2017). There is a lack of evidence around the severity of rubella infection in premature infants. In the case report by Klein et al. (1980), human milk transmission of wild-type rubella led to asymptomatic infection of an infant. Transmission of the vaccine strain of rubella has led to asymptomatic or mild rubella disease (Landes et al. 1980; Losonsky et al. 1982).

In comparison, infection of the foetus *in utero* can lead to congenital rubella syndrome. This is much more severe than postnatal infection. Congenital rubella syndrome can result in severe birth defects such as brain damage and heart defects (ATAGI 2018; CDC 2017).

[1] Rash with both flat and raised skin lesions

Infectivity
The infective dose of rubella in human milk is not known. When transmitted via the respiratory route rubella is very infectious, with an infectious dose of >10 viral units via pharyngeal spray or 60 viral units by nasal drops (PHAC 2017).

Risk mitigation
Controls are needed to minimise contamination of human milk with rubella, including pasteurisation of the milk. Rubella is inactivated by heat treatment at 56^{o}C for 2-20 minutes (Hobman 2013; PHAC 2017). Therefore Holder pasteurisation (62.5^{o}C, 30 min) will be effective at inactivating rubella. International human milk banks, including those in Australia, routinely perform Holder pasteurisation on human milk to ensure the microbiological safety of donor human milk (Bharadva et al. 2014; Hartmann et al. 2007; HMBANA 2015; UKAMB 2003).

Evaluation of uncertainty
There is uncertainty around the infectivity of rubella through human milk and the number of viral particles required for this method of transmission. If assumed to be the same as transmission via the respiratory route, rubella would be considered to have a medium level of infectivity in human milk.

Pooling of human milk from multiple donors is common practice amongst many human milk banks, and would dilute the viral load from a single donor, however some milk banks only pool milk from individual donors (Haiden and Ziegler 2016). The Australian Red Cross milk bank pasteurises human milk in single donor batches (Australian Red Cross 2018).

Risk characterisation
There is a low likelihood of exposure to rubella as there is limited evidence of the virus being detected in human milk and transmission to infants occurring via breast feeding. Although potentially only small quantities of virus are required to cause infection, in postnatally infected infants rubella can be asymptomatic or potentially cause disease of mild severity.

Therefore rubella in imported human milk and human milk products does not present a potential medium or high risk to public health and safety.

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References

ATAGI (2018) Australian immunisation handbook. Australian Technical Advisory Group on Immunisation, Australian Government Department of Health, Canberra. https://immunisationhandbook.health.gov.au/. Accessed 3 January 2019

Australian Red Cross (2018) Milk bank media release. Australian Red Cross Blood Service, Melbourne. https://www.donateblood.com.au/milk-bank-media. Accessed 2 July 2019

Bharadva K, Tiwari S, Mishra S, Mukhopadhyan K, Yadav B, Agarwal RK, Kumar V, Infant and Young Child Feeding Chapter, Indian Academy of Pediatrics (2014) Human milk banking guidelines. Indian Pediatrics 51:469–474

CDC (2017) Rubella (German measles, three-day measles). Centers for Disease Control and Prevention, Atlanta. https://www.cdc.gov/rubella/index.html. Accessed 4 January 2019

Codex (2012) Guidelines on the application of general principles of food hygiene to the control of viruses in food (CAC/GL 79-2012). Codex Alimentarius, Rome. http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/. Accessed 22 May 2018

Haiden N, Ziegler EE (2016) Human Milk Banking. Annals of Nutrition & Metabolism 69:8–15

Hartmann BT, Pang WW, Keil AD, Hartmann PE, Simmer K (2007) Best practice guidelines for the operation of a donor human milk bank in an Australian NICU. Early Human Development 83:667–673

HMBANA (2015) Guidelines for the establishment and operation of a donor human milk bank. Human Milk Banking Association of North America, Fort Worth

Hobman TC (2013) Rubella virus. In: Knipe DM, Howley PM (eds) Fields virology, 6th edition, Ch 24. Lippincott Williams & Wilkins, Philadelphia, pp 687–711

Klein EB, Byrne T, Cooper LZ (1980) Neonatal rubella in a breast-fed infant after postpartum maternal infection. The Journal of Pediatrics 97:774–775

Kuhn RJ (2013) Togaviridae. In: Knipe DM, Howley PM (eds) Fields virology, 6th edition, Ch 22. Lippincott Williams & Wilkins, Philadelphia, pp 629–650

Landes RD, Bass JW, Millunchick EW, Oetgen WJ (1980) Neonatal rubella following postpoartum maternal immunization. The Journal of Pediatrics 97:465-467

Losonsky GA, Fishaut JM, Strussenberg J, Ogra PL (1982) Effect of immunization against rubella on lactation products. II. Maternal-neonatal interactions. The Journal of Infectious Diseases 145:661–666

PHAC (2017) Pathogen safety data sheets: Infectious substances - Rubella virus. Public Health Agency of Canada, Ottawa. https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/rubella-virus.html. Accessed 31 January 2019

Stiehm ER, Keller MA (2001) Breast milk transmission of viral disease. Advances in Nutritional Research 10:105–122

UKAMB (2003) Guidelines for the establishment and operation of human milk banks in the UK. United Kingdom Association for Milk Banking, London. https://www.rcpch.ac.uk/sites/default/files/asset_library/Research/Clinical%20Effectiveness/Endorsed%20guidelines/Milk%20Banks/donor%20guidelines%203rd%20ed%20FINAL.pdf. Accessed 8 February 2018

WHO (2018) Rubella. World Health Organisation, Geneva. https://www.who.int/news-room/fact-sheets/detail/rubella. Accessed 3 July 2019