Infectious Disease (ID) Management Fact Sheet

This document was developed with our consulting Infectious Diseases and Obstetric Medicine Physician Dr Jill Parkes-Smith of Mater Mothers' Hospital, Brisbane, for the purpose of guiding clinicians when interpreting compulsory screening results for donors and the recommended management for the intended recipient/s.
For any non-compulsory results that come back as positive, the ordering/treating Fertility Doctor or Specialist has an obligation to ensure they are reviewed, communicated clearly to the patient and/or donor, and treated appropriately. These can be assessed on a case-by-case basis and consultation with ID specialist can be sought where needed.

Please refer to 'CMV fact sheet for clinicians' for further details on CMV management.

Donor Guidelines

Management when Donor is positive for compulsory screening

Ensure where a recipient seeks to proceed with treatment using donated gametes or embryos, or embryos created with donated gametes from a donor candidate who has tested positive to a compulsory infectious disease screening test, that they have been counselled by their treating Fertility Doctor or Specialist who must then clear them to proceed with treatment.

Infection	Donor type	Recipient Recruited Donor	Clinic Recruited Donor
HIV I & II **Positive HIV serology combined Ag/Ab**	Sperm, Egg, Egg or sperm source for embryo donation	Can proceed if: - Donor agreeable to disclose status - HIV viral load undetectable at least 6 months prior to donation - Advice sought from ID specialist - MAC/Local Donor Group approval - Risk Acknowledgement signed by recipient/s	- Donor not suitable for Clinic Recruited program and should be rejected if a true result - If uncertainty regarding interpretation, results reviewed by ID specialist
Hepatitis B **Positive Hep B sAg at any point**	Sperm, Egg, Egg or sperm source for embryo donation	Can proceed if: - Donor agreeable to disclose status - Advice sought from ID specialist - MAC/Local Donor Group approval - Risk Acknowledgement signed by recipient/s - Before recipient/s undertake treatment, they should be advised to be fully immunised against HBV if not already immune (HepB sAb >10 IU/ml)	- Donor not suitable for Clinic Recruited program and should be rejected if a true result - If uncertainty regarding interpretation, results reviewed by ID specialist

Infection	Donor type	Recipient Recruited Donor	Clinic Recruited Donor
Hepatitis B Positive Hep B Core Ab only	Sperm, Egg	Can proceed if: - Donor agreeable to disclose status - Recipient aware and accepts additional testing charges (Hep B viral load) - MAC/Local Donor Group approval - Hep B viral load undertaken 30 days prior to donation - If viral load result undetectable, donation can proceed - Hep B Viral load repeated post quarantine, if undetectable donation can be used - If viral load detectable- then proceed as per the Hep B sAg protocol above	- Donor not suitable for Clinic Recruited program and should be rejected if a true result - If uncertainty regarding interpretation, results reviewed by ID specialist
	Egg or sperm source for embryo donation	Can proceed if: - Donor agreeable to disclose status - Advice sought from ID specialist* - MAC/Local Donor Group approval - Risk Acknowledgement signed by recipient/s - Before recipient/s undertake treatment, they should be advised to be fully immunised against HBV if not already immune (HepB sAb >10 IU/ml)	- Donor not suitable for Clinic Recruited program and should be rejected if a true result - If uncertainty regarding interpretation, results reviewed by ID specialist
ID note on Hepatitis B: *When a Hep B positive individual is receiving treatment for Hep B and has an undetectable viral load, it doesn't mean that they cannot transmit infection. Any recipient using a donor who is positive for Hep B would be recommended to have detectable Hep B immunity with a detected surface antibody >10IU/ml.* *Vaccination course for Hep B can take 6 months for a full course to be completed. Recipients with previous vaccination is recommended to show detectable surface Antibodies.*			

Infection	Donor type	Recipient Recruited Donor	Clinic Recruited Donor
Hepatitis C Positive Hep C Ab	Sperm, Egg	Can proceed if: - Donor agreeable to disclose status - Recipient aware and accepts additional testing charges (Hep C viral load) - Risk Acknowledgement signed by recipient/s - Hep C viral load undertaken within 30 days of donation - If viral load result undetectable, donation can proceed - Hep C viral load repeated post quarantine, if undetectable donation can be used	- Donor not suitable for Clinic Recruited program and should be rejected if a true result - If uncertainty regarding interpretation, results reviewed by ID specialist
	Egg or sperm source for embryo donation	Can proceed if: - Donor agreeable to disclose status - ID specialist full review for case-by-case consideration - MAC/Local donor group approval - Risk Acknowledgement signed by recipient/s	- Donor not suitable for Clinic Recruited program and should be rejected if a true result - If uncertainty regarding interpretation, results reviewed by ID specialist
ID note on Hepatitis C: *For donors with previous Hep C (Positive IgG with undetectable viral load), a thorough risk assessment should be undertaken by the clinician to assess ongoing risk factors for re-acquisition of Hep C i.e. ongoing injecting drug use. If ongoing risk factors are present, donation should be rejected. When recipient/s are signing a risk acknowledgement, they should be counselled that Hep C can be re-acquired with new exposure by the donor, that there are window periods in terms of testing and that it is potentially transmissible via fertility treatment.*			

Infection	Donor type	Recipient Recruited Donor	Clinic Recruited Donor
Syphilis **Positive serology at any point if any of the following detected:** - EIA/CMIA - TPPA/TPHA **Even if RPR Non-reactive**	Sperm, Egg, Egg or sperm source for embryo donation	Can proceed if: -Treatment history obtained confirming antibiotics received (date, place, type and number of doses) -Review of previous and current serology results -There must be a 4-fold fall in the RPR within 12 months of treatment to proceed with donation -Results discussed with ID specialist to ensure appropriate treatment received -MAC/Local donor group approval Not able to proceed if: -RPR changes from pre to post quarantine by more than two-fold (gametes) If uncertainty regarding interpretation, results reviewed by ID specialist	Can proceed if: - Treatment history obtained confirming antibiotics received (date, place, type and number of doses) - Review of previous and current serology results - There must be a 4-fold fall in the RPR within 12 months of treatment to proceed with donation - Results discussed with ID specialist to ensure appropriate treatment received Not able to proceed if: - RPR changes from pre to post quarantine by more than two-fold (gametes) If uncertainty regarding interpretation, results reviewed by ID specialist
ID note on Syphilis: *All donors with detectable EIA and TPPA or EIA and TPHA even with non-reactive RPR should have their syphilis stage of disease and treatment history confirmed.* *Whilst it may not be infectious, we have a responsibility to ensure adequate treatment. Without adequate treatment the donors are at risk of neurosyphilis/tertiary syphilis. Cases are on the rise so vigilance to investigate each positive case is required.* *If the donor is unable to obtain records for treatment, we should not proceed with them as a donor until re-treatment due to potential risk of transmission/disease progression.*			
Gonorrhoea **Positive PCR**	Sperm, Egg (N/A embryo donors)	If detected prior to donation: -Treat and undertake a test of cure 7 days post treatment -Donation cannot proceed until treated and re-tested with a negative result -Sexual contacts should be tested/treated to reduce risk of re-infection If detected in following donation in post-quarantine results: -Any donations should be discarded	
Chlamydia **Positive PCR**	Sperm, Egg (N/A embryo donors)	If detected prior to donation: -Treat and undertake a test of cure 4 weeks post treatment -Donation cannot proceed until treated and re-tested with a negative result -Sexual contacts should be tested/treated to reduce risk of re-infection If detected in following donation in post-quarantine results:	

Infection	Donor type	Recipient Recruited Donor	Clinic Recruited Donor
		-Any donations should be discarded	
HTLV I & II Positive Abs/Viral DNA	Sperm	-Results should be reviewed by ID specialist -Donor not suitable for donor program and should be rejected if a true result and referred to ID specialist for personal management	

*For embryo donors ID specialist advice may be required due to the creation of embryos occurring in the absence of the compulsory screening tests (for sperm/egg source). A case-by-case assessment is often required.

Recipient Guidelines

Management when Recipient/Partner is positive for compulsory screening

Ensure where a recipient seeks to proceed with treatment using donated gametes or embryos, or embryos created with donated gametes and the recipient and/or partner has tested positive to a compulsory infectious disease screening test, that their results are reviewed by their treating Fertility Doctor or Specialist who must then clear them to proceed with treatment.

Infection	Patient (carrying pregnancy)	Partner (gamete provider)	Partner (not supplying gametes)
HIV I & II **Positive HIV serology combined Ag/Ab**	**Prior to treatment:** - Patient should be otherwise in good health and be suitable for treatment - Patient should be on combination antiretroviral therapy and have undetectable plasma viral load for a minimum of 6 months - Written confirmation should be sought from the treating ID/HIV specialist that pregnancy is safe to proceed - An obstetrician or obstetric unit should be designated to care for patients with HIV in pregnancy - The patient and partner (if applicable) need a Risk Acknowledgement explained, understood and signed - The patient and partner (if applicable) must understand that risk can be minimised of HIV transmission to a seronegative partner and child but never eliminated completely **During pregnancy:** - Patient should be maintained on pregnancy-suitable antiretrovirals and liaison with the patients' HIV/ID specialist should be sought. - As above, there should be an obstetrician or obstetric unit designated to manage the pregnancy to minimise the risk of vertical transmission and adhere to recommended mode of delivery and post-delivery recommendations, including counselling on feeding practices and infant follow up **Following birth:** - Infants born to a parent with HIV should be tested in first months of life to determine infant's infection status	<u>Sperm provider</u> **Prior to treatment:** - Plasma viral load undetectable for at least 6 months prior to providing sperm. **During treatment:** - Preparation of sample should be conducted in accordance with WHO guidelines - A combination of density-gradient centrifugation followed by swim-up separates virus-infected non-sperm cells and seminal plasma (in the density-gradient supernatant) from HIV-free motile spermatozoa in the swim-up (from the density-gradient pellet) - If IVF treatment, then ICSI should be used as the fertilization method to reduce the risk of HIV transmission to the embryo **Following treatment:** - HIV negative recipient should have follow-up HIV testing at 6 and 12 weeks	- To reduce the risk of transmission to the partner carrying the pregnancy or donating the gametes, the partner should have good disease control (i.e. undetectable viral load) or they should be using alternative means to reduce the risk of transmission (barrier, PrEP, abstinence) -The viral load of the partner does not need to be checked; however, counselling should be provided to the couple about the risks of transmission and the means to mitigate this risk -If more in depth counselling is required liaison with their HIV/ID specialist should be sought

	- Formula feeding reduces the risk of transmission, compared to breast/chest feeding and an informed discussion on safe infant feeding options should be undertaken in consultation with their HIV/ID specialist	<u>Egg provider</u> **Prior to treatment:** - Plasma viral load undetectable for at least the 6 months prior to providing eggs	
ID note on HIV: With effective antiretroviral treatment, the risk of vertical transmission from parent to child can be reduced from 25% to <1%.			
Hepatitis B **Positive Hep B sAg at any point**	**Prior to treatment:** - FBC and liver function tests should be checked to exclude evidence of underlying liver dysfunction/cirrhosis - If concerns (elevated ALT, AST, low platelets) seek specialist review prior to proceeding - Refer to an ID specialist or hepatology service for routine follow ups as they are at an increased risk of liver disease and hepatocellular carcinoma in the future and need long term surveillance **During pregnancy:** - Viral load should be checked at 28 weeks gestation to assess the need for anti-viral treatment in pregnancy to reduce the risk of transmission **Following birth:** - Infant will be offered vaccination and Hep B immunoglobulin	**Prior to treatment:** - Recipient/s or sexual partner should be advised to be fully immunised against HBV if not already immune (HepB sAb >10 IU/ml) -If the partner is not immune, barrier protection should be recommended until they are immune	
Hepatitis B **Positive Hep B core Ab only**	Immune due to resolved infection **Prior to treatment:** - Record result and recommend family screening through GP	Risk of transmission very low **Prior to treatment:** - Recipient/s or sexual partner should be advised to be fully immunised against HBV if not already immune (HepB sAb >10 IU/ml).	
Hepatitis C **Positive Hep C Ab**	**Prior to treatment:** - Hep C quantitative viral load undertaken - If the viral load is detectable, they should be recommended to undergo treatment for Hep C to reduce the risk of vertical transmission from carrier of pregnancy to child or horizontal transfer between partners (if applicable) - If the viral load is not detected, they do not have Hep C at this time and can proceed with treatment *(see below note regarding re-infection)*		**Prior to treatment:** - Hep C quantitative viral load should be checked if they have a detected Hep C antibody - If the viral load is detectable, treatment for Hep C should be recommended, and barrier protection used until treatment complete

		-They can proceed with fertility treatment in the interim if counselling is completed on avoiding contact with partner's blood and whilst, sexual transmission is uncommon, condoms will reduce the risk of transmission
ID note on Hepatitis C: Whilst sexual transmission of Hep C is an uncommon mode of transmission, it can be transmitted sexually. Treatment generally takes 8-12 weeks to complete and another 12 weeks to confirm that it has been successful. The risk of vertical transmission without treatment is about 5%. *Hep C re-infection can occur with re-exposure even after previous treatment or with spontaneous clearance. Hep C can be reacquired if risk factors remain.*		
Syphilis **Positive serology at any point if any of the following detected:** - EIA/CMIA - TPPA/TPHA **Even if RPR Non-reactive**	**Prior to treatment:** - Treatment history obtained confirming antibiotics received (date, place, type and number of doses) - Review of previous and current serology results - There should be a 4-fold fall in the RPR within 12 months of treatment to proceed with treatment - Results should be discussed with ID specialist if any uncertainty regarding adequacy of treatment	
HTLV I & II **Positive Abs/Viral DNA**	**Prior to treatment:** - Refer to ID specialist or liaise with existing specialist **Following birth:** - Counselling should be provided about the increased risk of transmission via breastmilk and alternative feeding methods explored to reduce the risk of transmission- i.e. formula feeding	**Prior to treatment:** - Refer to ID specialist or liaise with existing specialist
		Prior to treatment: - Couples should be counselled on the risk of transmission via sexual contact and the means to reduce this risk - Barrier protection can reduce the risk of transmission **Following birth:** - If partner breast/chest feeding, counselling should be provided about the increased risk of transmission via breastmilk and alternative feeding methods explored to reduce the risk of transmission- i.e. formula feeding

ID specialist review process

General questions can be directed to consults@drjill.com.au, these will be reviewed and triaged.

- Please note that Jill is an external contractor and a cost centre must be allocated for invoicing.

For recipients/donors who require a review directly with ID specialist, referral addressed to Jill Parkes-Smith can be emailed to consults@drjill.com.au

- Medicare details need to be provided for the patient/donor
- Provide any results or details that may be relevant
- A consult letter will be provided to the donor/recipient and referral specialist following the appointment