Guideline

Management of newborns born to women with HIV (Human Immunodeficiency Virus) Infection

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Custodian	Infectious Diseases Physician - Infection Management and Prevention services	**Approval date**	30/04/2025
Accountable Officer	Executive Director Medical Services	**Effective date**	01/05/2025
Applicable to	All CHQ clinical staff	**Review date**	30/04/2027

HUMAN RIGHTS

This governance document has been human rights compatibility assessed. Limitations identified were deemed justifiable indicating reasonable confidence that, if adhered to, there are no implications arising under the *Human Rights Act 2019.*

PURPOSE

This guideline provides best practice recommendations regarding management of infants born to women with HIV infection.

SCOPE

This Guideline provides information for all Children's Health Queensland (CHQ) clinical employees (permanent, temporary and casual) and all organisations and individuals acting as its agents (including Visiting Medical Officers and other partners, contractors, consultants and volunteers) caring for paediatric patients.

SUPPORTING DOCUMENTS

PROCEDURES, GUIDELINES, PROTOCOLS

- CHQ-PROC-01036 Antimicrobial: Prescribing and Management
- CHQ-GDL-01221 Immunisation Guideline for Medically at Risk Children

FORMS AND TEMPLATES

- CHQ C.GOV Individual Patient approval (IPA)– online IPA request

GUIDELINE

COMMUNICATION AND ASSESSMENT PRIOR TO BIRTH OF INFANT

When a pregnant woman with HIV infection is identified:

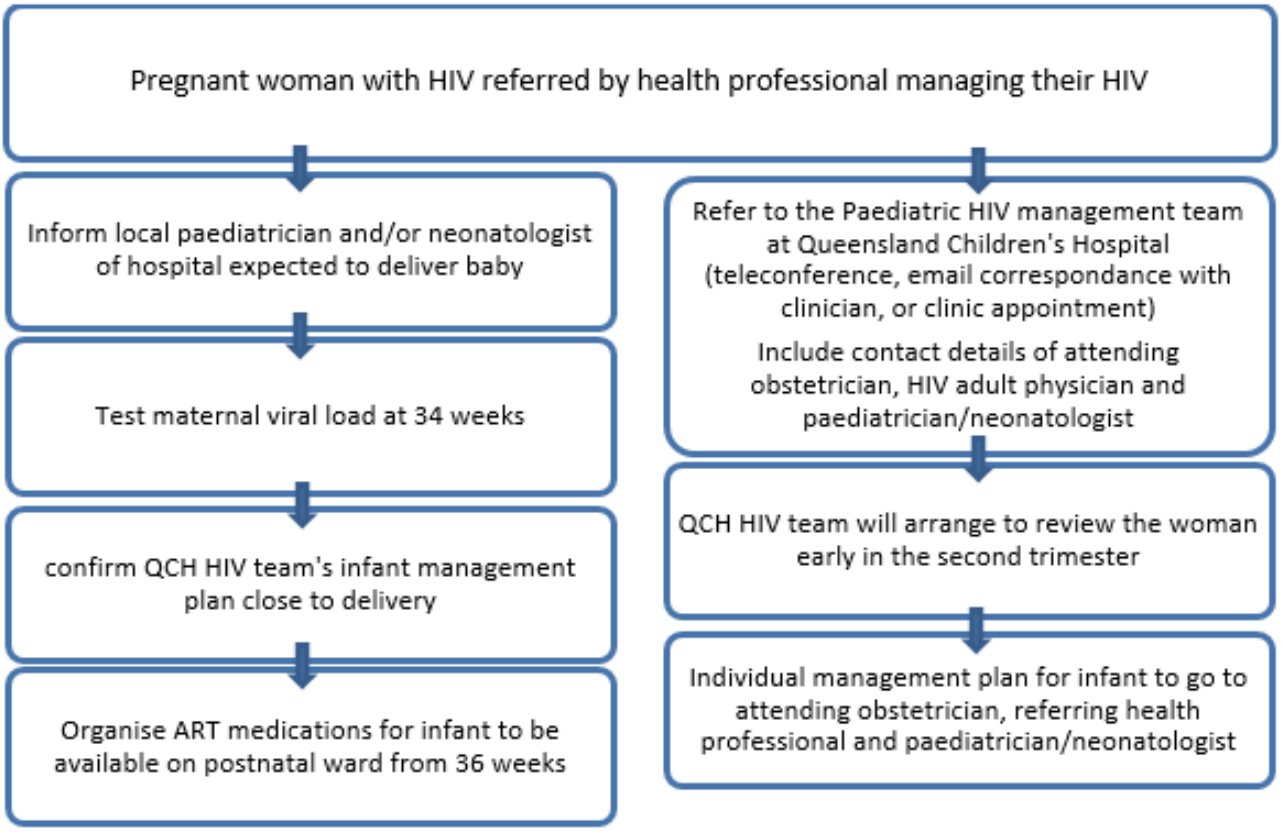
- Ensure referral to/attendance at Obstetrician and adult HIV physician for management (including delivery planning) for the pregnant woman.
- Inform local Paediatrician +/-Neonatologist at obstetric unit where infant expected to deliver.
- Refer woman to CHQ Infection Management and Prevention Service (IMPS) at Queensland Children's Hospital (QCH). Please include details of:
    - woman's antiretroviral treatment (ART)
    - most recent HIV test results (e.g. HIV viral load, HIV Proviral Deoxyribonucleic Acid (DNA) test result, CD4 (T-helper cells) count and HIV resistance tests), if available;
    - contact details for managing Obstetrician, HIV physician and Paediatrician/Neonatologist.
- To refer please complete the CHQ Specialist Referral form.
    - CHQ IMPS will arrange to review the woman in outpatient clinic early in the second trimester and will make recommendations for neonatal testing, treatment, and follow up.
    - For women residing outside of Brisbane, CHQ IMPS can offer advice by teleconference or by secure email with patient's consent.
- Ensure woman receives third trimester pertussis vaccination and seasonal influenza vaccine.

CHQ IMPS will provide an individual written/emailed management plan for the infant. This will be emailed/posted to attending Obstetrician, HIV adult physician and Paediatrician / Neonatologist.

As the plan will be contingent on maternal viral loads near delivery (e.g. 36 weeks gestation), the local Paediatrician or Neonatologist should review the management plan for the neonate when woman reaches the third trimester and confirm infant management plan with CHQ IMPS. Anticipated ART medications for the infant need to be available on the postnatal ward from 36 weeks gestation onwards.

In the event of a woman presenting for obstetric management late in pregnancy (e.g. in third trimester or in labour), CHQ IMPS should be contacted urgently before infant is delivered.

Figure 1. Referral pathway



RECOMMENDED ANTIRETROVIRAL TREATMENT (ART) FOR NEWBORN AND POST-NATAL CARE

A standard newborn assessment should be performed at birth by the local paediatric / neonatal team. Testing of newborn and ART should be commenced as soon as possible after delivery (ideally within 4 but no later than 12 hours). ART will continue for two (2) or four (4) weeks depending on risk of MTCT HIV (see Table 2).

Discharge infant with enough oral medications to complete two (2) or four (4) weeks of treatment. Please remind parent/carer to stop infant's ART at the correct time (Refer to Table 1 for more information) which will be before time of follow up appointment at six (6) weeks of age.

For infants of mothers with ART- resistant virus, please discuss infant ART regime with paediatric HIV specialist prior to birth. Individualised infant ART regimes may be indicated.

Figure 2. Management of infant born to woman with HIV infection (refer to Tables 1, 2, 4 and 5 for antiretroviral treatment dosing and duration recommendations for all age groups)

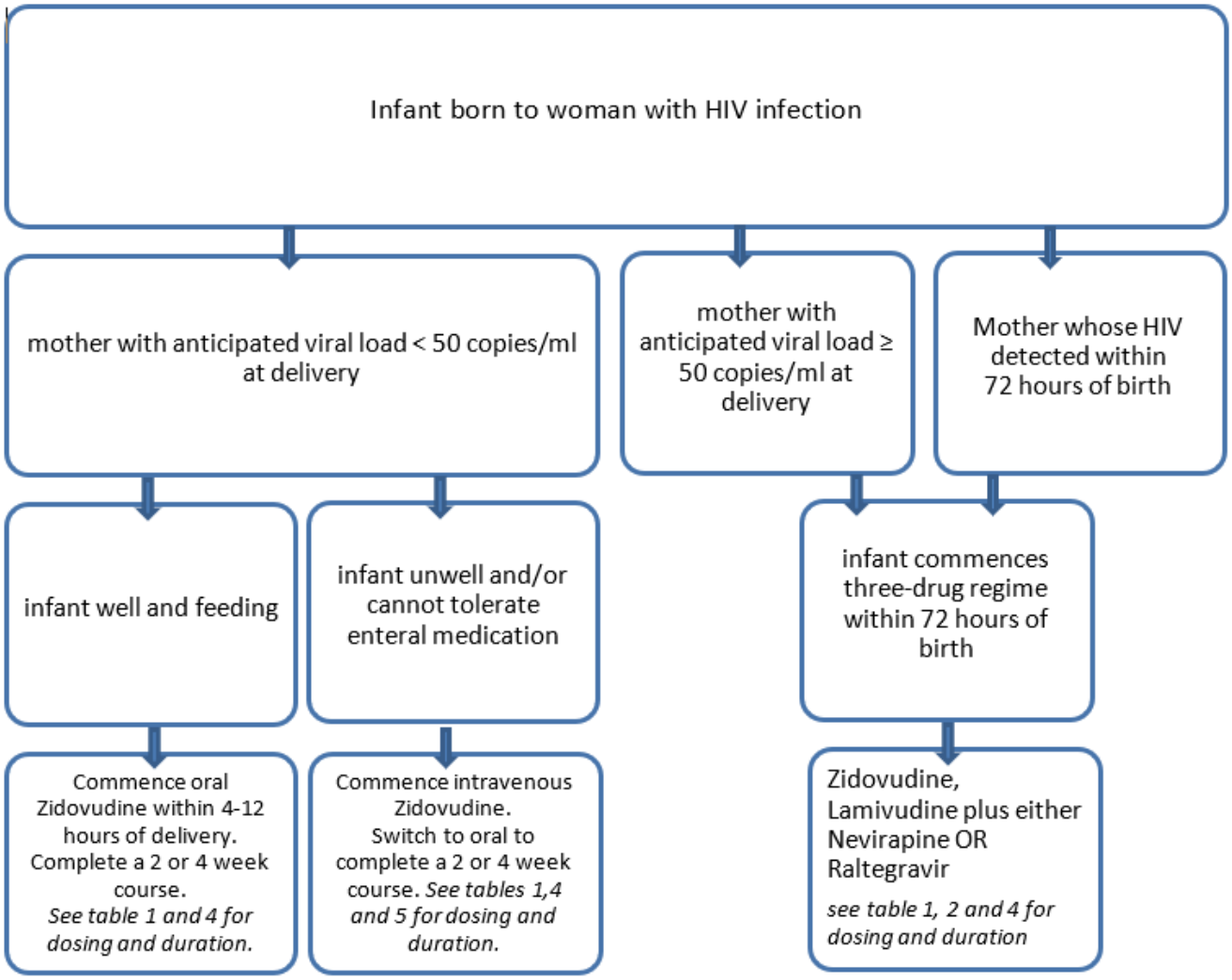


Table 1. Recommended antiretroviral treatment for infants born to HIV infected women (see Table 4)

Criteria	Gestation	Treatment
Very low risk **(Table 2)**	**Infants should commence treatment as soon as possible after birth with:**	
	More than 35 weeks	Zidovudine 4 mg/kg/dose orally 12 hourly for 2 weeks
	30 to 34 weeks	Zidovudine 2 mg/kg/dose orally 12 hourly for 2 weeks then 2 mg/kg/dose orally 8 hourly for 2 weeks (total treatment duration of 4 weeks).
	Less than 30 weeks	Zidovudine 2 mg/kg/dose orally 12 hourly for 4 weeks
Low risk Infants of pregnant women who have an undetectable viral load (less than 50 copies per mL) at delivery	**Infants should commence treatment as soon as possible after birth with:**	
	More than 35 weeks	Zidovudine 4 mg/kg/dose orally 12 hourly for 4 weeks.
	30 to 34 weeks	Zidovudine 2 mg/kg/dose orally 12 hourly for 2 weeks then 2 mg/kg/dose orally 8 hourly for 2 weeks (total treatment duration of 4 weeks).
	Less than 30 weeks	Zidovudine 2 mg/kg/dose orally 12 hourly for 4 weeks
High risk Infants born to pregnant women who have detectable viral load > 50 copies/ml at delivery **OR** Infants born to pregnant women who are not on therapy / present late or in labour / without testing available **OR** Women whose HIV infection is detected after birth (infant treatment indicated if within 72 hours of infant's birth)	**Infants should commence 3-drug treatment as soon as possible after birth (and no later than 72 hours after birth if maternal HIV is diagnosed late)**	
	More than 35 weeks	A. Zidovudine 4 mg/kg/dose orally every 12 hours for 4 weeks (total treatment duration of 4 weeks). B. Lamivudine 2 mg/kg/dose orally every 12 hours for 4 weeks (total treatment duration of 4 weeks). **C.** Nevirapine 2 mg/kg/dose, once daily for first week then 4 mg/kg/dose once daily for second week, then stop (total treatment duration of 2 weeks due to long half-life of nevirapine). **If mother has received nevirapine for 3 or more days just before delivery:** Neonatal metabolism of nevirapine has been induced. Hence the full dose of 4mg/kg/dose once daily should be commenced at birth and continued for 2 weeks. If unavailable, give oral Raltegravir (see table 2 for dosing recommendation).
	30 to 35 weeks	A. Zidovudine 2 mg/kg/dose orally every 12 hours for 2 weeks then every 8 hours for 2 weeks (total treatment duration of 4 weeks). B. Lamivudine 2 mg/kg/dose orally every 12 hours for 4 weeks. (total treatment duration of 4 weeks). C. Nevirapine 12 mg per dose (or 8 mg per dose if less than 2kg) orally for 3 doses in the first week of life. Give 1st dose within 48hrs of birth, then the 2nd dose 48 hours after 1st dose followed by the 3rd dose 96 hrs after 2nd dose (total treatment duration of 1 week due to long half-life of nevirapine). If unavailable, give oral Raltegravir (see table 2 for dosing recommendation).
	Less than 30 weeks	A. Zidovudine 2 mg/kg/dose orally every 12 hours for 2 weeks then 3 mg/kg/dose orally every 12 hours for 2 weeks (total treatment duration of 4 weeks). B. Lamivudine 2 mg/kg/dose orally every 12 hours for 4 weeks (total treatment duration of 4 weeks). C. Nevirapine 12 mg per dose (or 8 mg per dose if less than 2 kg) orally for 3 doses in the first week of life. Give 1st dose within 48 hrs of birth, then the 2nd dose 48 hours after 1st dose followed by the 3rd dose 96 hours after 2nd dose. (Total treatment duration of 1 week due to long half-life of nevirapine). If unavailable, Oral Raltegravir (see table 2)

Table 2 Recommended oral Raltegravir dosing for neonates/ infants

(≥ 37 weeks gestation and ≥2 kg birth weight, week 1 to 4 of life) born to HIV infected women

Age and weight	**Raltegravir Dose[$]** **(Use 10mg/mL Raltegravir suspension*)**
Birth to 1 Week of Age: Once Daily Dosing	**Approximately 1.5 mg/kg per dose**
2 kg to <3 kg	0.4 mL (4 mg) once daily
3 kg to <4 kg	0.5 mL (5 mg) once daily
4 kg to <5 kg	0.7 mL (7 mg) once daily
1 to 4 Weeks of Age: Twice-Daily Dosing	**Approximately 3 mg/kg per dose**
2 kg to <3 kg	0.8 mL (8 mg) twice daily
3 kg to <4 kg	1 mL (10 mg) twice daily
4 kg to <5 kg	1.5 mL (15 mg) twice daily
Footnotes: $ If the mother has taken Raltegravir or Dolutegravir 2 to 24 hours prior to delivery, the neonate's first dose of Raltegravir should be delayed until 24 to 48 hours after birth; additional ART drugs should be started as soon as possible. * Raltegravir 10mg/mL granules for suspension and chewable tablets (25mg, 100mg) are not bioequivalent. Raltegravir 10mg/mL granules for suspension is not TGA registered and only available via the Special Access Scheme. SAS and an Individual Patient Approval (IPA) is required.	

For more information: Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection | NIH

Table 3 Recommended oral Dolutegravir dosing for infants more than 4 weeks of age

Weight (>4 weeks of age)	**Dolutegravir Dose** (use DTG dispersible tablets*)
3 to 5.99 kg	5 mg once daily
6 to 9.99 kg	15 mg once daily
10 to 13.99 kg	20 mg once daily
14 to 19.99 kg	25 mg once daily
≥ 20 kg	30 mg once daily
* Film coated tablets are not bioequivalent to dispersible tablets Avoid antacids/mineral supplements containing polyvalent cations 6 hours before & 2 hours after taking – seek advice	

Table 4 Risk assessment to determine duration of ART neonates

Very Low Risk • Mother has been on ART for longer than 10 weeks **AND** • Two documented maternal HIV viral loads <50 copies/mL during pregnancy at least 4 weeks apart **AND** • Maternal HIV viral load <50 copies/mL at or after 34 weeks	**2 to 4 weeks** of zidovudine monotherapy is recommended (regardless of feeding method) (see Table 1 for duration)
Low Risk • If the criteria for "Very Low Risk" are not fulfilled but maternal HIV viral load is <50 copies/mL at or after 34 weeks; **OR** • If the baby is born prematurely (<34/40) but most recent maternal HIV viral load is <50 copies/mL	**4 weeks** of zidovudine monotherapy
High Risk • If maternal birth HIV viral load is known to be or likely to be ≥50 copies/mL on day of birth, if uncertainty about recent maternal adherence or if viral load is not known	**Combination ART for 4 weeks**

Zidovudine monotherapy is recommended if maternal transmission risk is low (woman has an undetectable viral load) even if the pregnant woman has a previous history of Zidovudine resistance.

Newborns who are unwell and/or cannot tolerate oral Zidovudine can be given intravenous Zidovudine (**Please note**: IV dose is 75 % of the oral dose administered at the same interval – refer to Table 4).

Table 5. Recommended intravenous Zidovudine dosing for pre-term and term neonates/ infants (week 1 to 4 of life) born to HIV infected women

Gestation	Postnatal age	Treatment
More than 35 weeks	Days 1 to 28 of life	Zidovudine IV 1.5 mg/kg/dose every 6 hourly
30 to 35 weeks	Days 1 to 14 of life	Zidovudine IV 1.5 mg/kg/dose every 12 hourly
	Days 15 to 28 of life	Zidovudine IV 2.3 mg/kg/dose every 12 hourly
Less than 30 weeks	Days 1 to 28 of life	Zidovudine IV 1.5 mg/kg/dose every 12 hourly

The intravenous formulation of Zidovudine is not TGA registered and only available via the Special Access Scheme. SAS and an Individual Patient Approval (IPA) is required.

There is no intravenous formulation for Lamivudine or Nevirapine. These medications should commence as soon as possible after delivery but within 72 hours of birth and only if the newborn is able to tolerate enteral medications.

ZIDOVUDINE CAUTION

Results of a French National Trial using Zidovudine and Lamivudine to prevent vertical transmission highlighted a concern in that two (2) out of 200 babies studied developed an extremely rare and fatal neurological disease. Similar clinical findings have not been confirmed at any other centres although the potential for nucleoside analogues to interfere with mitochondrial function is recognised. The possibility of mitochondrial toxicity must be considered in babies exposed to ART who present unwell to your service. Manifestations include lactic acidosis and disturbed neurological findings.

For information about drug interactions with ART: University of Liverpool HIV Drug Interaction Checker (www.hiv-druginteractions.org).

MODE OF FEEDING

Formula feeding is generally recommended for all infants born to women with HIV infection. However, in particular circumstances, where the woman is adherent to her ARV regimen and has maintained a suppressed viral load during pregnancy (or at least during the third trimester of pregnancy), and is fully engaged in her own care, consideration can be given (after consultation with the Paediatric Infection Specialist) to supporting breast feeding for a maximum period of 6 months.

The mother will be counselled specifically about the risk of transmission associated with breastfeeding, and the indications for when BF should be ceased eg. bleeding nipples, maternal gastroenteritis etc.

Additional 1-2 monthly testing of both mother and infant during breast feeding will be required. If mother's VL becomes detectable during breastfeeding, breastfeeding should be ceased immediately, and the Paediatric Infection Specialist consulted.

If a breastfeeding mother's VL becomes detectable, post exposure prophylaxis may be offered to the breastfed infant which may include dolutegravir (> 4 weeks of age), zidovudine and lamivudine for four weeks. Cabergoline may be recommended for the mother to suppress lactation.

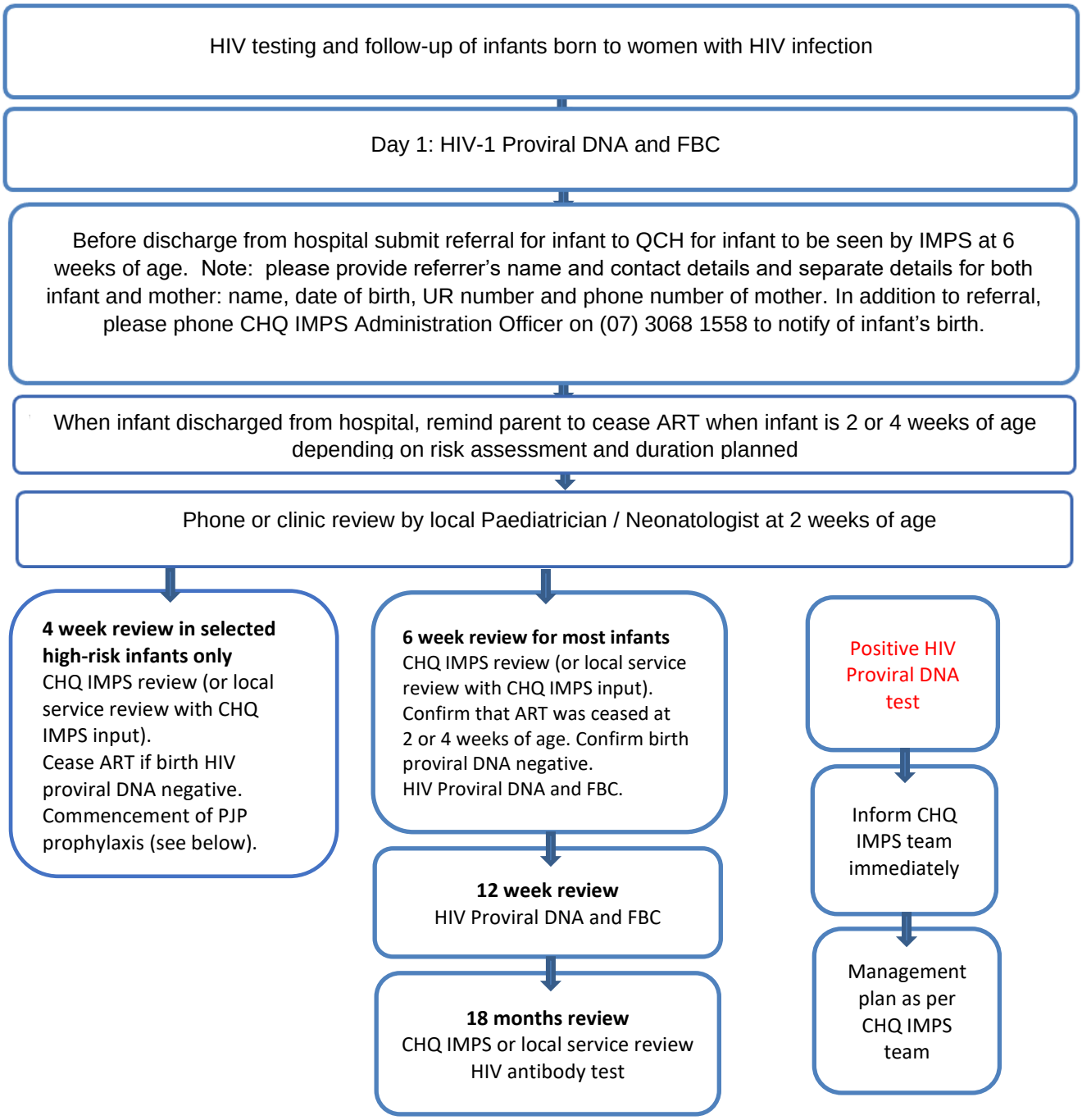
HIV TESTING AND FOLLOW-UP OF THE INFANT (SEE FIGURE 3)

HIV testing of the infant is required on day one (1) of life. Blood must be taken from the newborn and **NOT** from umbilical cord. HIV ribonucleic acid (RNA) viral load is no longer available for the purposes of HIV diagnosis, hence testing of exposed infants is with HIV Proviral DNA.

Blood tests that are taken on day one (1) and at follow-up appointments are:

- HIV Proviral DNA (1 mL whole blood – EDTA, minimum testing required); and
- Full Blood Count (FBC).

Figure 3. HIV testing and follow-up of infants born to women with HIV infection



A positive HIV test result within 72 hours of birth is taken as evidence of intrauterine transmission.

Babies who are not breastfed and who have a HIV Proviral DNA Polymerase Chain Reaction (PCR) test that is negative up to and including the test at three (3) months of age are not HIV infected.

All babies born to HIV positive pregnant women will have passively acquired Immunoglobulin G (IgG) antibodies to HIV. The median time to loss of antibody is ten months, but it may be as long as 18 months.

If birth, six week and three-month HIV Proviral DNA tests are negative, then one further test (HIV antibody only) is indicated at 18 months of age to document clearance of maternal HIV antibodies.

If infant is breastfed, more frequent HIV Proviral DNA testing is recommended while the infant is breastfed, and one month and three months after cessation of breastfeeding.

Yearly follow-up is recommended for the exposed but not infected child particularly in the first five (5) years of life to assess health and developmental progress.

PNEUMOCYSTIS JIROVECI PNEUMONIA (PJP) PROPHYLAXIS

- In HIV infected children, PJP occurs most frequently between three and six months of age. Trimethoprim/Sulfamethoxazole is recommended from four weeks of age **ONLY** for babies considered to have a high risk of acquiring HIV from their mother. If the HIV proviral DNA PCR at three months of age is negative PJP prophylaxis is discontinued.
- Trimethoprim/Sulfamethoxazole dose is 5 mg/kg/day (Trimethoprim component) (orally) in 1 to 2 divided doses daily (equates to approximately 0.63 mL/kg/day of the 8/40 mg/mL oral suspension).

IMMUNISATION OF THE INFANT BORN TO WOMAN WITH HIV INFECTION

- HIV exposed uninfected infants (HEU) babies should receive immunisations as per the National Immunisation Program. If Bacille Calmette-Guerin (BCG) vaccination at birth is indicated, it is deferred and can be given usually at three months of age if three Proviral DNA tests are negative.
- HEU infants born to mothers not on ART at conception are recommended to receive NIP plus additional pneumococcal vaccinations as per Australian Immunisation Handbook recommendation for people with medical risk factors.

HIV INFECTED CHILDREN WILL RECEIVE ADDITIONAL VACCINES INCLUDING YEARLY INFLUENZA VACCINES- FOLLOW QCH HIV SERVICE/IMMUNISATION SERVICE ADVICE. TESTING FOR OTHER INFECTIONS

- Babies at risk of HIV may also be at risk of other infections. If the mother is found to have Hepatitis B Virus, Hepatitis C Virus or Syphilis then the infant will need appropriate evaluation.

CONSULTATION

Key stakeholders who reviewed this version:

• Paediatric Infection Specialist – HIV Medical Lead • Paediatric Infection Specialist • Director of IMPS, Immunology and Rheumatology	• Clinical Nurse Consultant, Paediatric HIV service • Pharmacist Advanced - Antimicrobial Stewardship • Medicines Advisory Committee endorsed 17/04/2025

ABBREVIATIONS

AMS	Antimicrobial Stewardship
ART	Anti-retroviral treatment
BCG	Bacille Calmette-Guerin (Mycobacterium tuberculosis vaccine)
CD4	*Refers to* CD4 or T-helper cells
CHQ	Children's Health Queensland
DNA	Deoxyribonucleic acid
EDTA	Ethylenediaminetetraacetic acid
FBC	Full blood count
HIV	Human Immunodeficiency Virus
ID	Infectious Diseases specialist
IgG	Immunoglobulin G
IMPS	Infection Management Prevention Service
PCR	Polymerase Chain Reaction
PJP	Pneumocystis jiroveci pneumonia
RNA	Ribonucleic acid
QCH	Queensland Children's Hospital
VL	Viral load

REFERENCES AND SUGGESTED READING

No.	Reference
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2.	British HIV Association guidelines for the management of pregnancy in women living with HIV infection 2020. Available online BHIVA guidelines for the management of HIV in pregnancy and postpartum 2018 (2020 third interim update) - update this ??? to 2024 - consultation
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11.	Antiretroviral and HIV drug dosing for children and adolescents 2024 – 2026 guideline from the Imperial College Healthcare NHS Trust on the Children's HIV Association website

GUIDELINE REVISION AND APPROVAL HISTORY

Version No.	Modified by	Amendments authorised by	Approved by	Comments
1.0	Infectious Diseases Consultant Team (IMPS) Infectious Diseases Fellow (IMPS) Pharmacist Advanced - AMS (QCH)	Medicines Advisory Committee (QCH)	Executive Director Medical Services	

2.0	Infectious Diseases Consultant Team (IMPS) Pharmacist Advanced - AMS (QCH)	Medicines Advisory Committee (QCH)	Executive Director Medical Services	
3.1 28/05/2019	Infectious Diseases Consultant Team (IMPS) Pharmacist Advanced - AMS (QCH)	Medicines Advisory Committee (QCH)	Executive Director Clinical Services (QCH)	
4.0 29/07/2021	Paediatric Infection Specialist (IMPS) Pharmacist Advanced - AMS (QCH)	Service Group Director – IMPS Medical Director – Division of Medicine	Executive Director Clinical Services	
5.0 08/12/2022	Senior Medical Officer, IMPS	Service Group Director – IMPS	A/Divisional Director Medicine	
6.0	Paediatric Infection Specialist (IMPS) Pharmacist Advanced - AMS	Medicines Advisory Committee	Executive Director Clinical Services	
7.0 03/09/2024	Paediatric Infection Specialist (IMPS) Pharmacist Advanced - AMS	Medicines Advisory Committee	Executive Director Clinical Services	Scheduled review and transition to new template
8.0 30/04/2025	Paediatric Infection Specialist (IMPS) HIV CNC Pharmacist Advanced - AMS	Medicines Advisory Committee	Executive Director Clinical Services	Unscheduled review

Key words	Human immune deficiency virus, HIV, newborn, perinatal HIV, HIV and pregnancy, antiretroviral agent, ART, nevirapine, zidovudine, lamivudine, antimicrobial stewardship, IMPS, AMS, ID, mother to child transmission, 01243
Accreditation references	The National Safety and Quality Health Service (NSQHS) Standards (1-8): • Standard 3: Preventing and Controlling Healthcare Associated Infections; • Standard 4: Medication Safety.