Antiretroviral / HIV Drug Dosing for Paediatrics 2015 - Imperial College Healthcare NHS Trust

(NOT for neonatal vertical transmission post exposure prophylaxis – see local / BHIVA guidelines)

Agent	Recommended dosage, class side effects and contraindications & warnings	Formulation	Comment	Intake Advice
Nucleoside Reverse Transcriptase Inhibitors (NRTI): lactic acidosis, steatosis, Lipoatrophy (effects of mitochondrial toxicity)				
Lamivudine (3TC) Epivir® / Zeffix® *(ViiV/GSK)*	**Child**: (≥3months) 4 mg/kg BD or 8mg/kg OD. Well tolerated round up doses. Max dose 300mg per day **Paed dosing for 150mg tab**: (14-19kg) →½ tab BD or 1 tab OD, (>20-24kg) → ½ tab AM + 1 tab PM or 1½ tab OD, (>25kg) →1 tab BD or 2 tabs OD. **Adult:** (≥12 years) 150mg BD or 300mg OD Nausea, diarrhoea, headache, fatigue.	**Tab**:100mg *(Zeffix)* (orange) 150mg *(Epivir)* (white) scored 300mg *(Epivir)* (grey) Generic tabs scored appearance varies **Liq**: 10mg/ml(*Epivir*) (30 day expiry)	Arrow study suggests full dose 3TC is safe/effective if >25kg; Reduce in renal failure	With or without food. Can be crushed and mixed with small amount of water or food.
Abacavir (ABC) Ziagen® *(ViiV)*	**Child:** (≥3months) 8mg/kg BD or 16mg/kg OD. Well tolerated round up doses. Max dose: 600mg per day **Paed dosing for 300mg tab**: (14-19kg) → ½ tab BD or 1tab OD, (>20-24kg) ½ tab AM + 1 tab PM or 1½ tab OD, (>25kg) → 1 tab BD or 2 tabs OD **Adult:** (≥12 yrs): 300mg BD or 600mg OD **Test HLA-B*5701 before starting, do not give abacavir if HLA-B*5701 +ve.** Hypersensitivity reactions (usually within 1st 6 weeks of therapy), rare in Afro-Caribbeans, require careful evaluation. **If proven, not to be given again** Nausea, fever, headache, diarrhoea, rash, fatigue, respiratory symptoms	**Tab**: 300mg (yellow) scored **Liq**: 20mg/ml (60-day expiry)	Arrow study suggests full dose ABC may be safe/effective if >25kg; but no long term safety data yet.	With or without food. Can be crushed and mixed with small amount of water or food.
Zidovudine (AZT) Retrovir® *(ViiV)*	**Child:** 180mg/m² BD. (max. dose 300mg BD) **IV dosing**: 60-80mg/m² QDS (total daily dose may be given in 2 divided doses) **Paed dosing for capsules**: (8-13kg) →100mg BD, (14-21kg) → 100mg morning + 200mg night, (22-28kg) → 200mg BD (>28kg) → 250mg BD. **Adult:** 250mg BD (300mg BD for Combivir or Trizivir combinations). Granulocytopenia and/or anaemia, nausea, headache, myopathy, hepatitis, nail pigmentation, neuropathy.	**Cap**: 100mg(white) 250mg (white/blue) - Generic Caps – Appearance may vary **Liq**: 10mg/ml – 1 month expiry after opening **IV infusion**: 10mg/ml (200mg/20ml vial)	Do not give with stavudine.	With or without food. Capsules can be opened and dissolved in water.
Emtricitabine (FTC) Emtriva® *(Gilead)*	**Child:** (≥ 4months) 6mg/kg OD of the oral solution. (max. dose 240mg OD) **Adult:** Capsule (≥33kg) 200mg OD; oral solution: 240mg OD Headache, diarrhoea, nausea, rash, skin discolouration on palms and soles (more prominent in non-Caucasians).	**Cap**: 200mg (blue/white)≡240mg liq **Liq**: 10mg/ml - Fridge (Discard 45 days after opening) - **not** bioequivalent to caps. Capsules contents can be dispersed in water	Reduce dose in renal Impairment. Do not give with lamivudine	With or without food.
AZT + 3TC Combivir® *(ViiV)*	**Child:** (14-21kg) ½ tab BD (21-30kg) ½ tab AM + 1 tab PM (≥30kg) 1 tab BD **Adult:** (>30kg)→ 1 tab BD	**Tab**: AZT 300mg/3TC 150mg (White) Generic tab scored – appearance varies	Can be cut or crushed just before giving	With or without food.
ABC + 3TC Kivexa® *(ViiV)*	**Child:** Not recommended <25kg use individual ARV's **Adult :** (>25kg)→ 1 tab OD ***See abacavir for HLA-B*5701 testing requirements***	**Tab**: ABC 600mg/3TC 300mg (Orange)	See 3TC and ABC	With or without food.
ABC + 3TC + AZT Trizivir® *(ViiV)*	**Child:** Not recommended <30kg use individual ARV's **Adult:** (>30kg)→ 1 tab BD ***See abacavir for HLA-B*5701 testing requirements***	**Tab**: AZT/ABC/3TC 300/300/150 (green)	Not to be cut	With or without food.
Nucleotide Reverse Transcriptase inhibitors (NtRTI): As NRTI's				
Tenofovir disproxil (TD) Viread® *(Gilead)* **Note: 245mg tenofovir disoproxil (TD) ≡ 300mg tenofovir disoproxil fumarate (TDF)**	***All doses now based on Tenofovir Disoproxil (TD)*** **Child powder dosing:** (2 – 12yrs) 6.5mg/kg OD - **1 scoop (scp) = 33mg** (10-12kg) → 2 scp, (12-14kg) → 2.5 scp, (14-17kg) → 3 scp, (17-19kg) → 3.5 scp (19-22kg) → 4 scp, (22-24kg) → 4.5 scp, (24-27kg) → 5 scp, (27-29kg) → 5.5 scp (29-32kg) → 6 scp, (32-34kg) → 6.5 scp, (34-35kg) →7 scp, (≥35kg) 7.5 scp. **Paed tab dosing:** (17-22kg): 123mg OD, (23-28kg) 163mg OD, (28-34kg) 204mg OD, (≥35kg): 245mg OD **Adult:** (≥35kg) 245mg OD. Headache, nausea, vomiting, renal tubular dysfunction, bone demineralization, exacerbations of hepatitis on discontinuation. **Important: Renal function, blood and urine monitoring.**	**Tab**: TD 245mg (blue) **Paed tab TD (TDF)**: 123mg (150mg), 163mg (200mg), 204mg (250mg) **Powder**: TD 33mg/1g per scoop (TDF 40mg/1g per scoop)	Dose reduction in renal impairment. Careful monitoring with boosted PI regimens for renal toxicity . Can cut or disperse tabs in water or orange juice or grape juice, but bitter taste	Take with food
TD + FTC *Truvada® (Gilead)*	**Child:** Not recommended <35kg use individual ARV's **Adult:** (> 35kg)→ 1 tab OD	**Tab**: TD 245mg/FTC 200mg (blue)		
Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI) Do TDM for both NNRTs and PIs in combination. Do TDM with Rifamycins. Long half-life consider cover with PI after stopping				
Nevirapine (NVP) Viramune® Viramune-XR® *(Boehringer)*	**Child lead in period:** 150-200mg/m² OD for 14 days (max 200mg/day), then if no rash or LFT abnormalities increase to 150-200mg/m² BD or 300-400mg/m² OD – Max 400mg/day - **XR tabs not suitable for lead in period**. **Adult:** 200mg OD for 14 days, then increase to 200mg BD or 400mg OD if no rash or LFT abnormalities. Rash, hepatitis, Steven-Johnson – usually first 12 weeks. **Check hepatic function at 2, 4, and 8 weeks.**	**Tab**: 200mg [Generic available] **Liq**: 10mg/ml (Shake well) **Prolonged-release tabs**: (all yellow) 50mg,100mg, 400mg	Normal release tabs can be cut. Normal dose in renal impairment. Do not cut PR tabs	With or without food. Some patients have reported the tablet remnant in faeces – not known to affect response.
Efavirenz (EFV) Sustiva® (*BMS*)	**Child: (≥3months):** (3.5-<5kg) →100mg OD, (5-<7.5kg) → 150mg OD, (7.5-<15kg) → 200mg OD, (15-<20kg) → 250mg OD, (20-<25kg) →300mg OD, (25-<32.5kg)→ 350mg OD, (32.5-<40kg)→ 400mg OD **Adult:** (>40kg) → 600mg OD ***As per PENTA 2015 guidelines, not recommended for patients <3 years*** Mood changes, vivid dreams (common but usually short lived), hypercholesterolemia, rash, gynaecomastia	**Cap**: 50mg (Yellow/White), 200mg (yellow) **Tab**: 600mg [Generic available) Capsules can be used as sprinkles	No dose adjustments in renal impairment. 600mg Tablet can be cut. ***Higher EFV levels in CYP2B6-TT Genotype***	Take on empty stomach preferably before bedtime. Caps can be opened and added to liquids or 1-2 teaspoons of food. ***High fat meal can ↑EFV AUC by 30% and ↑adverse reactions.***
Etravirine (ETR) Intelence® *(Janssen)*	**Child: (>6 years):** (16-<20kg)→100mg BD, (20-<25kg)→125mg BD, (25-<30kg)→150mg BD, (≥30kg)→200mg BD **Adult:** (≥30kg) 200mg BD **Investigational adult dose**: 400mg OD Dizziness, diarrhoea, flatulence, abdominal pain, headache, pruritis, rash. Rash usually resolves in 1-2 weeks	**Tab (dispersible):** 25mg, 100mg, 200mg (white)	AUC decreased by 50% if taken on empty stomach	Take with food. All tablets dispersible in water.
TD + FTC + EFV Atripla® *(Gilead)*	**Child:** individual TDF, FTC & EFV – max. dose as for adults **Adult:** (> 35kg) → 1 tab OD	**Tab**:TD 245mg /FTC 200 mg /EFV 600mg (pink)	Do not cut/crush	Take on empty stomach, preferably at bedtime.
RPV + TD + FTC **Rilpivirine (RPV)** Eviplera® *(Gilead)*	**Child:** No data in children **Adult:** (>35kg) → 1 tab OD ***MUST be with >390 calories*** **Rilpivirine single agent: Adult:** 25mg od with food >500 calories if without tenofovir Rilpivirine: Headache, dizziness, mood changes, diarrhoea (less frequent than EFV,) see TD/FTC	**Tab:** TD 245mg/FTC 200mg/RPV 25mg **Tab:** Rilpivirine (Eudrant) 25mg	Do not cut/crush. Avoid in VL>100,000 copies/ml. PPIs contraindicated (↓ RPV exposure).	Take with food. RPV AUC 40% lower on empty stomach. If dyspepsia, use Gaviscon or ranitidine 12-hours apart from Eviplera dose

Agent	Recommended dosage, class side effects, contraindications & warnings	Formulation	Comment	Intake Advice
Protease Inhibitors (PI): Lipodystrophy, hyperlipidaemia, diabetes mellitus, important interactions with a range of other drugs. If on dual PI, NNRTI or TB therapy need TDM				
Lopinavir/ritonavir (LPV/RTV) Kaletra® *(Abbvie/Abbott)*	***All doses based on lopinavir - PLEASE SPECIFY FORMULATION WHEN PRESCRIBING*** **Child Liquid:** (<15kg)→300mg/m² BD, (>15kg)→230-300 mg/m² BD (max. 400mg BD). **Dose in mls = (300 or 230) x SA / 80** **Paed tab dosing:** (15-<25kg)→ 2 tabs BD, (25-<35kg)→ 3 tabs BD, (>35kg)→ 4 tabs BD. **Adult:** (>35kg) 400mg BD = 2 adult tabs BD [= 4 paed tabs BD = 5ml BD of solution] Cautious use with hepatic insufficiency. Diarrhoea, headache, nausea, vomiting.	**Tab (adults):** LPV/RTV 200/50mg (yel) **Tab (paed):** LPV/RTV 100/25mg (yel) **Liq**: 5ml = LPV/RTV 400/100mg (clear) – Fridge (contains 42% ethanol and propylene glycol) - caution in neonates.	Licensed 230 mg/m²/BD → lower trough levels, clinicians may consider using 300mg/m²/BD. Do NOT use once daily	**Liq**: Take with food **Tab**: Can be given with or without food (no data in <18 years of age)
Darunavir (DRV) Prezista® *(Janssen)*	**Child: 3- 6 years with no DRV-resistance mutations** DRV 35mg/kg/OD + RTV 7mg/kg/OD**: (10-11kg)**→360mg OD + RTV 64mg OD**, (11-12kg)**→ 400mg + RTV 64mg OD**, (12-13kg)** → 420mg + RTV 80mg OD**, (13-14kg)** →460mg + RTV 80mg OD, **(14-15kg)** → 500mg + RTV 96mg**. ≥ 6 years:** (**15-30kg)** → 600mg OD + RTV 100mg OD, **(30-40kg)** 675mg OD + RTV 100mg OD, **(≥40kg)** →800mg + RTV 100mg OD, ***(DRV-resistance mutations 3-6 years:****(10-11kg)→ 200mg BD + RTV 32mg BD, (11-12kg)→ 220mg BD + RTV 32mg BD, (12-13kg)→ 240mg BD + RTV 40mg BD, (13-14kg)→ 260mg BD + RTV 40mg BD, (14-15kg)→ 280mg BD + RTV 48mg BD* ***≥6 years****: (15-30 kg) → 375mg DRV BD + RTV 50mg BD, (30-40 kg) → 450 mg DRV BD + RTV 60mg BD, (>40kg) → 600mg DRV BD + RTV 100mg BD.* **Adult:** (No DRV-resistance mutations): 800mg OD + RTV 100mg OD (DRV resistance mutations): 600mg BD + RTV 100mg BD Rash, nausea, diarrhoea, headache. **Contains sulphonamide moiety–check allergies esp Co-trimoxazole (Septrin)**	**Tab**: 75mg (white), 150mg (white), 400mg (light orange), 600mg (orange) & 800mg (dark red) **Liq:** 100mg/ml	Tablets can be cut/crushed if necessary.	Take with food. Some patients may be allergic to iron oxide in 800mg tablet formulation. 400mg tablets are available for these patients or where 800mg tablet too big.
Atazanavir (ATV) Reyataz® *(BMS)*	**Child: (>6years)** (15-<20kg)→150mg OD + RTV 100mg OD, (20-<40kg)→ 200mg OD + RTV 100mg OD, (>40kg)→ 300mg OD + RTV 100mg OD **Adult:** 300mg OD with RTV 100mg OD Nausea, headaches, rash, jaundice	**Caps**: 150mg (dark blue/light blue), 200mg (dark blue), 300mg (dark blue/red) Capsules can be opened and contents mixed with water/apple sauce	PPIs contraindicated (↓ATV exposure).	Take with food. If dyspepsia, use Gaviscon or ranitidine 12-hours apart from dose.
Ritonavir (RTV) Norvir® *(Abbott)*	**Child: For boosting other PIs see specific drug. Not recommended as a single PI**. **Adult: For boosting other PIs**: 100mg OD or 100mg BD e.g. with ATV or DRV Perioral paraesthesia, nausea, diarrhoea, flushing, rash, hepatitis with treatment dose	**Tab**: 100mg (white) **Liq**: 80mg/ml (contains 42% ethanol)- Store at room temp.	When purchasing ritonavir liquid consider relatively short expiry.	With or after food. Chocolate milk may help with bitter taste. Do not crush tablets
	Fusion & Entry Inhibitors: Hypersensitivity to peanut or soya			
Enfuvirtide (T-20) Fuzeon® *(Roche)*	**Child: (6 -16 yrs):** 2mg/kg BD sub-cutaneous. (max. dose 90mg BD) *NOT for 1st line HAART* **Adult (≥16 years):** 90mg BD sub-cutaneous injection Local injection site reactions common, less common bacterial pneumonia.	**Inj:** 108mg/1.1ml vial for subcutaneous injection (90mg/1ml) Clear	Limited data on IV dosing. SC route the preferred route	S/C injection (upper arm, thigh abdomen) – see product information
Maraviroc (MVC) Celsentri® *(Pfizer)*	**Child:** seek specialist advice ***ONLY FOR CCR5 TROPIC VIRUS*** **ASSAY FOR CO-RECEPTOR TROPISM WITHIN 3 MONTHS OF STARTING MVC** **Adult:** 150mg BD (with CYP3A4 inhibitor), 600mg BD (with CYP3A4 inducer), 300mg BD (with NVP) **Unlicensed dose in Adult**:150mg to 300mg OD (with boosted PI) Nausea, diarrhoea, headache, dizziness, pruritus, insomnia, altered parameters (ALT, AST, Lipase, ANC)	**Tabs**: 150mg, 300mg (blue)	**Always check dosing with pharmacy. Tablets can be cut/crushed**	With or without food.
Integrase Inhibitors - separate all integrase inhibitors from all oral cations (e.g. calcium/ magnesium/ iron/aluminium/zinc) including multivitamin/mineral products by 4 hours either side of dose				
Raltegravir (MK518) Isentress® *(MSD)*	**Child:** (≥4 wks): **6mg/kg/dose BD** as **Oral Suspension:** (max 100mg BD) or **Chewable tabs:** (max 300mg BD) **(3-3.9kg)**→1ml (20mg) BD, **(4-5kg)**→1.5ml (30mg) BD, **(6-7kg)**→2ml (40mg) BD, **(8-10kg)**→3ml (60mg) BD, **(11-13kg)**→4ml (80mg) BD or 3 x 25mg chewable tabs BD, **(14-19kg)**→5ml (100mg) BD or 1 x 100mg chewable tab BD, **(20-24kg)**→1½ x 100mg chewable tabs BD, **(25-27kg)**→1½ x 100mg chewable tabs BD or 1 x 400mg film coated tab BD, **(28-39kg)**→2 x 100mg chewable tabs BD or 1 x 400mg film coated tab BD, **(>40kg)**→3 x 100mg chewable tabs BD or 1 x 400mg film coated tab BD **Film coated tab (NB: not bioequivalent to suspension/chewable tabs above**): (>25kg) 400mg BD **Adult** (>25kg)**:** 400mg BD Nausea, dizziness, insomnia, rash, pancreatitis, elevated ALT, AST, Gamma GT	**100mg sachets for oral suspension:** 20mg/ml **Tab**: 400mg tabs (pink) **Chewable tab**: 25mg and 100mg (can be halved)	Suspension and Chewable tabs are **not bioequivalent** to standard tabs 400mg Tablets can be cut/crushed	With or without food. Avoid indigestion remedies (see heading)
ELV/COB/TD/FTC Stribild® *(Gilead)*	**Child**: No data in children /adolescents **Adult:** (>35kg) 1 tab OD Elvitegravir/Cobisistat: diarrhoea, rarely nausea, elevated serum creatinine with decrease in GFR	**Tab:** ELV 150mg/COB 150mg/FTC 200mg/TD 245mg (Green)	Licensed >18 years only. Avoid in GFR<70mL/min	Take with food Avoid indigestion remedies (see heading)
Dolutegravir (DTG) Tivicay® (*ViiV*)	**Child: (>12 years & >40kg) - Integrase Naïve:** 50**mg OD**, **Integrase resistance:** 50**mg BD** **Investigational child dose:** (6-12 years) 1**mg/kg OD** **Adult: Integrase Naïve:** 50**mg OD**, **Integrase resistance:** 50**mg BD** Hypersensitivity reaction (severe rash, fever, malaise, muscle/joint pain, oral blisters, conjunctivitis, facial oedema), insomnia, headache, transaminase elevation in underlying hepatitis B or C.	**Tab:** 50mg tabs (pale yellow) **Can be cut/crushed**	With inducers of CYP3A/UGT1A e.g. efavirenz, nevirapine, rifampicin use dolutegravir 50mg **BD**	Take with food (High fat significantly increases absorption). Avoid indigestion remedies (heading)
DTG/3TC/ABC Triumeq® (*ViiV*)	**Child:** (>12 years >40kg): 1 tab OD ***Test HLA-B*5701 before starting, do not give abacavir if HLA-B*5701 +ve*** Hypersensitivity reaction, insomnia, headache, transaminase elevation, nausea, fever, diarrhoea, rash, fatigue, respiratory symptoms	**Tab:** DTG 50mg/3TC 300mg/ABC 600mg (pale grey/purple) **Can be cut/crushed**	Can be used in VL>100,000	With or without food, with food preferred (see DTG). Avoid indigestion remedies (see heading)
Co-trimoxazole Septrin® Bactrim®	***PCP prophylaxis: Daily dosing preferred*** **Child:** (3-5.9kg) → 60mg OD, (6-13.9kg) → 120mg OD, (14-24.9kg) → 240mg OD, (>25kg)→ 480mg OD	**Tab**:480mg (white) **Liq**: 240mg/5ml (paed),480mg/5ml (adult)		With or without food.

The PAEDIATIC VIRTUAL CLINIC takes place on the 1st Thursday of the month. Please consider referring any child starting ART, with virological failure/resistance, requiring simplification or on older more toxic drugs for review . Email: caroline.foster@imperial.nhs.uk

Mosteller surface area equation:

$$BSA(m^2) = \sqrt{\frac{height(cm) \times weight(kg)}{3600}}$$

Important notes: Doses are not necessarily manufacturers' recommended dose and may not be licensed in children. Patients with renal/liver impairment may require dose modification, discuss with a pharmacist.
To ensure accurate dosing always use oral/enteral syringes to measure liquid medicines. Prescribers should round up doses to the nearest 'sensible' measurable volume/dose
Always check potential drug interactions between all ARVs and with concomitant therapy see www.hiv-druginteractions.org
TDM available for majority classes of ARV including NRTI's, NNRTI's PIs, Entry/Fusion/Integrase Inhibitors available via www.Lab21.com
Information in this table is not exhaustive and full prescribing information should be reviewed concomitantly. Prescribers retain responsibility for all prescribing decisions.

This table was prepared as the consensus view of the Imperial College HCT's Family Clinic November 2015. The table is intended to be used by practitioners experienced in paediatric HIV care. Please do not use this outside these recommendations.
The table will be reviewed in November 2016
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IMPLEMENTATION

Training required for staff	No
If yes, who will provide training	N/A
When will training be provided?	N/A
Date for implementation of guideline	Immediate

MONITORING / AUDIT

When will this guideline be audited?	n/a
Who will be responsible for auditing this guideline?	
Are there any other specific recommendations for audit?	

REVIEW

Who will review this guideline?	Caroline Foster / Neil Tickner / Hermione Lyall
Please indicate frequency of review:	2 years
Date of next review	October 2017

REFERENCES

BNF-C 2014-15, Summary of Product Characteristics for individual drugs.

GUIDELINE DETAIL

Start Date (date of final approval by Division)	immediate	
Dates approved by:	Paediatric Guidelines Group (if applicable)	Aim for Nov 2015
	Children's Quality and Safety meeting	Aim for Nov 2015
Have all relevant stakeholders (Trust sites, Divisions and departments) been included in the development of this guideline?	ARG – date TBC	
Who will you be notifying of the existence of this guidance?	All paediatric medical and nursing staff. All pharmacy staff	
Related documents:	HIV in Neonates: Prevention of Vertical Transmission. Post-Exposure Prophylaxis (PEP) Guidelines for children and adolescents potentially exposed to blood-borne viruses	
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Document review history:	2nd Edition	
Next review due	October 2016	
THIS GUIDELINE REPLACES:	Paediatric HIV Drug Dosing Chart 2014	

11) INTRANET HOUSEKEEPING

Key words (This should include all drugs that are mentioned in the guideline)	HIV, antiretroviral, ARV, lamivudine, abacavir, zidovudine, emtricitabine, combivir, kivexa, AZT, trizivir, tenofovir, truvada, nevirapine, efavirenz, etravirine, atripla, eviplera, kaletra, lopinavir, darunavir, atazanavir, ritonavir, enfuvirtide, T-20, maravirox, raltegravir, stribild, dolutegravir, triumeq, septrin, co-trimoxazole
Which Division does this belong to?	Division D
Which subdivision of the guidelines spine should this belong to?	Paediatric Infectious diseases
Title for the intranet if different from the document (please note that documents sit alphabetically so should not start with "guideline for…")	

Equality Impact of guideline

Is this guideline anticipated to have any significant equality-related impact on patients, carers or staff?

No