Supplementary Figure 1

Number of children who received booster dose and available for follow-up visits according to study group

HIV-unexposedd

N=110

HEUc

N=115

ART-Defb

N=69

ART-Immeda

N=171

**Pre-booster time-point: 15.5 months of agee**

Included in booster ATP N=146

Unavailable sample=22

Miss visit=3

Included in booster ATP N=61

Unavailable sample=8

Included in booster ATP N=114

Unavailable sample=1

Included in booster ATP N=107

Unavailable sample=2

Unable/unwilling to adhere to study protocol =1

**Post-booster time-point: 15.9 months of age**

Included in post-booster ATP N=52

Unavailable sample=7

Miss visit=1

Withdrew=1

Unable/unwilling to adhere to study protocol =10

Included in post-booster ATP N=103

Miss visit=3

Withdrawal=1

Unable/unwilling to adhere to study protocol =8

Included in post-booster ATP N=135

Unavailable sample=19

Miss visit=5

Withdrawal=2

Unable/unwilling to adhere to study protocol =10

Included in post-booster ATP N=100

Unavailable sample=2

Miss visit=1

Unable/unwilling to adhere to study protocol =7

**24 months of age time-point: 25.3 months of age**

Included in 24 months of age ATP N=122

Unavailable sample=21

Miss visit=11

Loss to follow up=7

Withdrawal=3

Deceased=1

Unable/unwilling to adhere to study protocol =6

Included in 24 months of age ATP N=50

Unavailable sample=8

Miss visit=4

Loss to follow up=1

Unable/unwilling to adhere to study protocol =6

Included in 24 months of age ATP N=97

Unavailable sample=2

Miss visit=7

Withdrawal=2

Lost to follow up=3

Unable/unwilling to adhere to study protocol =4

Included in 24 months of age ATP N=97

Unavailable sample=2

Miss visit=8

Withdrawal=1

Unable/unwilling to adhere to study protocol =2

Supplementary Figure 1.Reasons for exclusion from analyses at the different study time-points.

aART-Immed: HIV-infected children with CD4+% ≥25% at enrolment who were initiated on antiretroviral therapy (ART) at enrolment; bART-Def: HIV-infected children with CD4+ ≥25% at enrolment randomized to deferred ART; cHEU: HIV-uninfected children born to HIV-infected mothers; dHIV-unexposed: HIV-uninfected children born to HIV-uninfected mothers; ePre-booster: 15.5 months of age, all children received a booster dose of DTP and no booster dose of hepatitis-B vaccine was administered.

Explanatory notes: ATP: analysis time-point; Unavailable sample: sample unavailable for further testing; Lost to follow-up: due to relocation or the children stopped the study without reason; Withdrew: parent or guardian withdrew informed consent; Missed visit: children missed a schedule visit; Unable/unwilling to adhere to study protocol.

Number of participants who left the study (excluded, missed visit, lost to follow-up, withdrawals, deceased) are represented as cumulative pre- and post-vaccination.

Supplementary Table 1: Comparison of children included in analysis versus those not included in analysis.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Variable** | **All children included** | | **Children excluded from the current analysis** | | **p-value** | |
| Number | 465 | | 29 | |  | |
| Male, n (%) | 218 (47) | | 19 (65) | | 0.051 | |
| Black race, n (%) | 420 (90) | | 29 (100) | | 0.079 | |
| Coloured race, n (%) | 45 (10) | | 0 (0) | |
| Soweto study center, n (%) | 312 (67) | | 25 (86) | | 0.032 | |
| Stellenbosch study center, n (%) | 153 (33) | | 4 (14) | |
| Mean time in months between last dose in primary series and  booster dose (±SD) | 12.0 (0.6) | | 12.9 (2.1) | | <0.001 | |
| Mean age in months (±SD) | 15.5 (0.5) | | 15.3 (0.4) | | 0.148 | |
| Pre-boostera |  | |  | |  | |
| Post-boosterb | 15.9 (0.5) | | 15.8 (0.5) | | 0.454 | |
| 24 months of age | 25.3 (0.6) | | 25.4 (0.6) | | 0.388 | |
|  | ART-Immed. | ART-Def | ART-Immed. | ART-Def | p-valuec | p-valued |
| Total initiated ART between first and last dose of primary series n/N (%) | 146/146 (100) | 9/61 (15) | 25/25 (100) | 2/8 (25) | NEe | 0.539 |
| Total on ART between last dose of primary series and booster dose n/N (%) | 146/146 (100) | 52/61 (85) | 25/25 (100) | 7/8 (88) | NE | 0.962 |
| Time to ART initiation relative to dose 1 of primary series, median months (range) | ND | 4 (3 to 8) n=59 | ND | 3 (2 to 4) n=7 | ND | 0.183 |

aBlood draw was undertaken just prior to and on the same day of DTP booster vaccination; bChildren who received booster dose within protocol-defined window periods and available immunogenicity data within 1-2 weeks after booster; cp-value ART-Immed. all children included compared to ART-Immed. children excluded from the current analysis; dp-value ART-Def all infants included compared to ART-Def Infants excluded from the current analysis;eNE: not evaluable; fND: not done.

Supplementary Table 2. Geometric mean concentrations and proportion of children in the two ART Immed groups with sero-protective antibody titers and sero-conversion rates at pre-booster, post-booster and at 2 years of age

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Antibody | Threshold | Time-point | ART/12ma N=70 | ART/24mb N=76 | p-value |
| TT | GMC | Pre-Booster | 0.08  (0.06-0.09) | 0.08  (0.07-0.10) | 0.40 |
| Post-booster | 7.3  (6.1-8.9) | 6.0  (4.9-7.4) | 0.24 |
| Fold-changec | 100.5  (76.0-133.1) | 78.1  (58.0-105.0) | 0.45 |
| 24 months | 0.74  (0.60-0.92) | 0.82  (0.68-0.98) | 0.32 |
| Fold-changed | 8.7  (6.7-11.3) | 11.3  (9.3-13.7) | 0.15 |
| ≥0.01 | Pre-booster: N/n; % (95% CI) | 69/70; 99  (92-100) | 76/76; 100  (95-100) | *0.30* |
| Post-booster: N/n; % (95% CI) | 63/63; 100  (94-100) | 72/72; 100  (95-100) | NEe |
| 24 months: N/n; % (95% CI) | 56/56; 100  (94-100) | 66/66; 100  (95-100) | NE |
| ≥0.1 | Pre-booster: N/n; % (95% CI) | 36/70; 51  (40-63) | 36/76; 47  (37-58) | 0.38 |
| Post-booster: N/n; % (95% CI) | 63/63; 100  (94-100) | 72/72; 100  (95-100) | NE |
| 24 months: N/n; % (95% CI) | 56/56; 100  (94-100) | 66/66; 100  (95-100) | NE |
| ≥1 | Pre-booster: N/n; % (95% CI) | 0/70; 0 | 1/76; 1  (0.2-7) | *0.34* |
| Post-booster: N/n; % (95% CI) | 61/63; 97  (89-99) | 69/72; 96  (88-99) | 0.97 |
| 24 months: N/n; % (95% CI) | 18/56; 32  (21-45) | 26/66; 39  (28-51) | 0.96 |
| DT | GMC | Pre-Booster | 0.10  (0.9-0.12) | 0.10  (0.08-0.11) | 0.72 |
| Post-booster | 3.2  (2.9-3.7) | 2.8  (2.3-3.2) | 0.23 |
| Fold-change | 33.1  (26.6-41.4) | 28.1  (21.8-36.3) | 0.71 |
| 24 months | 0.45  (0.38-0.54) | 0.47  (0.39-0.55) | 0.91 |
| Fold-change | 4.2  (3.3-5.3) | 5.0  (4.1-6.1) | 0.45 |
| ≥0.01 | Pre-booster: N/n; % (95% CI) | 70/70; 100  (95-100) | 76/76; 100  (95-100) | NE |
| Post-booster: N/n; % (95% CI) | 63/63; 100  (94-100) | 72/72; 100  (95-100) | NE |
| 24 months: N/n; % (95% CI) | 56/56; 100  (94-100) | 66/66; 100  (95-100) | NE |
| ≥0.1 | Pre-booster: N/n; % (95% CI) | 40/70; 57  (46-68) | 39/76; 51  (40-62) | 0.84 |
| Post-booster: N/n; % (95% CI) | 63/63; 100  (94-100) | 72/72; 100  (95-100) | NE |
| 24 months: N/n; % (95% CI) | 56/56; 100  (94-100) | 65/66; 98.5  (92-100) | *0.36* |
| ≥1 | Pre-booster: N/n; % (95% CI) | 0/70; 0 | 0/76; 0 | NE |
| Post-booster: N/n; % (95% CI) | 61/63; 97  (89-99) | 64/72; 89  (80-94) | 0.12 |
| 24 months: N/n; % (95% CI) | 7/56; 13  (6-24) | 9/66; 14  (7-24) | 0.75 |
| HBsAg | GMC | 15-18 months | 721.5  (573.6-907.5) | 816.4  (647.0-1030.1) | 0.74 |
| 24 months | 211.8  (174.4-257.1) | 271.1  (220.6-33.2) | 0.67 |
| Fold-change | 0.33  (0.24-0.45) | 0.34  (0.25-0.46) | 0.75 |
| ≥10 | 15-18 months: N/n; % (95% CI) | 70/70; 100  (95-100) | 76/76; 100  (95-100) | NE |
| 24 months: N/n; % (95% CI) | 56/56; 100  (94-100) | 66/66; 100  (94-100) | NE |
| ≥100 | 15-18 months: N/n; % (95% CI) | 68/70; 97  (90-99) | 74/76; 97  (91-99) | 0.86 |
| 24 months: N/n; % (95% CI) | 53/56; 95  (85-98) | 59/66; 89  (80-95) | 0.34 |
| FHA | GMC | Pre-Booster | 36.1  (30.4-42.8) | 32.2  (27.6-37.5) | 0.60 |
| Post-booster | 437.1  (354.3-539.4) | 416.5  (346.9-500.0) | 0.99 |
| Fold-change | 12.8  (9.5-17.3) | 13.2  (10.3-17.0) | 0.55 |
| 24 months | 208.3  (159.7-271.8) | 190.4  (157.9-229.5) | 0.74 |
| Fold-change | 5.5  (4.1-7.5) | 6.1  (4.8-7.7) | 0.74 |
| ≥4 fold | Post-booster: N/n; % (95% CI) | 56/63; 90  (80-96) | 60/69; 87  (77-93) | 0.68 |
| PT | GMC | Pre-booster | 30.5  (26.2-35.6) | 33.0  (28.6-37.5) | 0.04 |
| Post-booster | 953.3  (741.9-1224.9) | 949.9  (749.4-1203.9) | 0.46 |
| Fold-change | 31.0  (22.6-42.5) | 29.3  (22.4-38.2) | 0.94 |
| 24 months | 255.3  (212.6-306.6) | 253.9  (214.5-300.6) | 0.98 |
| Fold-change | 8.3  (6.8-10.2) | 8.0  (6.4-10.0) | 0.83 |
| ≥4 fold | Post-booster: N/n; % (95% CI) | 59/63; 95  (87-98) | 67/69; 97  (90-99) | 0.52 |

Footnote: Geometric mean concentration (95% confidence interval); Percentage of participants with concentration above threshold (95% confidence interval); Units for antibody to TT, DT, PT and FHA are IU/ml; Units for HBsAg are mIU/ml. aART/12m: HIV-infected children with CD4+ ≥25% at enrolment who were initiated on ART at enrolment and in whom ART was interrupted at 12-months of age; bART/24m: HIV-infected children with CD4+ ≥25% at enrolment who were initiated on ART at enrolment and in whom ART was interrupted at 24-months of age; dFold-change: Fold-change in GMC between pre-booster and post-booster; eFold-change: Fold-change in GMC between post-booster and 24 months of age; eNE: not evaluable.

Explanatory notes:

p-values were either calculated by linear or logistic regression and adjusted for age, gender, race, study center, pre-booster antibody concentration (for post-booster and 24 months of age time-points) and CD4+ cell percentage in HIV-infected children; or by Pearson’s chi-square test for values in italics. Similar results were obtained by univariate analysis.

Supplementary Table 3. Geometric mean concentrations at pre-booster, post-booster and at 24 months of age

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Antibody | Threshold | Time-point | HIV-unexposeda  N=107 | ART-Immedb  N=146 | p-valuec | ART-Defd  N=61 | p-valuee | p-valuef | HEUg  N=114 | p-valueh |
| TT | GMC | Pre-Booster | 0.13  (0.12-0.15) | 0.08  (0.07-0.09) | <0.001 | 0.11  (0.08-0.15) | 0.09 | 0.07 | 0.13  (0.12-0.15) | 0.47 |
| Post-booster | 17.9  (15.8-20.4) | 6.6  (5.7-7.6) | <0.001 | 4.4  (3.2-6.1) | <0.001 | 0.01 | 15.4  (13.3-17.9) | 0.72 |
| Fold-changei | 135.6  (114.1-161.0) | 87.9  (71.7-107.7) | <0.001 | 39.8  (23.0-68.8) | <0.001 | 0.001 | 116.6  (97.5-139.3) | 0.72 |
| 24 months | 1.7  (1.5-1.9) | 0.79  (0.69-0.90) | <0.001 | 0.23  (0.15-0.35) | <0.001 | <0.001 | 1.3  (1.1-1.5) | 0.01 |
| Fold-changej | -10.1 (8.7-11.8) | -9.7 (8.0-11.7) | 0.74 | -21.3 (13.8-32.7) | <0.001 | 0.002 | -11.9 (9.8-14.5) | 0.08 |
| DT | GMC | Pre-Booster | 0.08  (0.07-0.09) | 0.10  (0.09-0.11) | 0.22 | 0.12  (0.10-0.15) | 0.05 | 0.05 | 0.07  (0.05-0.09) | 0.07 |
| Post-booster | 3.9  (3.5-4.3) | 3.0  (2.7-3.3) | 0.15 | 2.3  (1.8-3.0) | 0.003 | 0.04 | 4.6  (4.1-5.2) | 0.002 |
| Fold-changei | 49.6  (41.4-59.4) | 30.4  (25.7-36.0) | 0.08 | 17.9  (12.2-26.2) | 0.001 | 0.001 | 68.4  (48.9-95.8) | 0.004 |
| 24 months | 0.68  (0.60-0.77) | 0.46  (0.41-0.52) | <0.001 | 0.20  (0.15-0.27) | <0.001 | <0.001 | 0.61  (0.53-0.70) | 0.37 |
| Fold-changej | -5.5 (4.8-6.4) | -6.8 (5.8-8.0) | 0.008 | -11.4 (8.3-15.7) | 0.001 | 0.008 | -7.7 (6.5-9.1) | 0.004 |
| FHA | GMC | Pre-booster | 24.6  (20.9-28.9) | 34.0  (30.3-38.1) | 0.001 | 31.9  (26.9-38.0) | 0.09 | 0.23 | 34.5  (30.1-39.6) | 0.01 |
| Post-booster | 467.6  (395.8-552.4) | 426.0  (371.6-488.3) | 0.71 | 402.2  (324.9-497.9) | 0.78 | 0.50 | 806.2  (703.2-924.2) | <0.001 |
| Fold-changei | 18.7  (14.8-23.6) | 13.0  (10.8-15.8) | 0.22 | 12.3  (9.1-16.6) | 0.36 | >0.99 | 23.1  (19.0-28.1) | 0.01 |
| 24 months | 170.3  (151.2-191.8) | 198.4  (169.7-232.0) | 0.26 | 103.9  (70.3-153.7) | 0.02 | 0.001 | 140.9  (120.1-165.4) | 0.14 |
| Fold-changej | -2.6 (2.1-3.2) | -2.1 (1.7-2.6) | 0.40 | -3.6 (2.3-5.6) | 0.04 | 0.03 | -5.8 (4.8-7.0) | <0.001 |
| PT | GMC | Pre-booster | 38.3  (33.9-43.3) | 31.8  (28.7-35.2) | 0.004 | 27.2  (21.6-34.2) | 0.004 | 0.38 | 39.5  (35.3-44.3) | 0.64 |
| Post-booster | 2168.8  (1856.7-2533.3) | 951.5  (802.7-1127.8) | <0.001 | 767.6  (594.8-990.7) | <0.001 | 0.19 | 3138.2  (2650.6-3715.5) | <0.001 |
| Fold-changei | 56.1  (45.6-69.0) | 30.1  (24.6-36.8) | 0.01 | 27.9  (18.3-42.5) | 0.04 | 0.89 | 79.7  (65.7-96.7) | 0.001 |
| 24 months | 268.4  (228.3-315.5) | 254.6  (225.3-287.7) | 0.54 | 67.2  (47.9-94.3) | <0.001 | <0.001 | 348.6  (288.6-421.2) | 0.09 |
| Fold-changej | -7.7 (6.1-9.7) | -4.0 (3.3-4.9) | 0.001 | -12.0 (8.6-16.7) | 0.01 | <0.001 | -9.6 (7.6-12.2) | 0.06 |
| HBsAg | GMC | 5 monthsk | 2521.0  (2249.8-2824.9) | 924.9  (778.3-1099.1) | <0.001 | 536.6  (373.0-772.0) | <0.001 | 0.02 | 2019.3  (1740.3-2343.0) | 0.04 |
| 15-18 months | 1198.5  (1033.9-1389.4) | 769.4  (654.4-904.7) | 0.001 | 700.2  (587.3-834.7) | 0.002 | 0.55 | 880.1  (719.2-1077.0) | 0.02 |
| Fold-changel | -2.1 (1.8-2.5) | -1.2 (0.9-1.5) | <0.001 | 0.8 (0.50-1.3) | <0.001 | 0.13 | -2.3 (1.8-3.0) | 0.78 |
| 24 months | 396.1  (332.5-471.8) | 242.0  (209.9-279.1) | 0.001 | 54.8  (32.2-93.0) | <0.001 | <0.001 | 311.9  (264.8-367.4) | 0.11 |
| Fold-changem | -3.0 (2.5-3.7) | -3.0 (2.4-3.7) | 0.94 | -13.3 (7.6-23.2) | <0.001 | <0.001 | -3.0 (2.3-4.0) | 0.97 |

Footnote: Geometric mean concentration (95% confidence interval); Units for geometric mean concentration (GMC) are IU/ml for TT, DT, FHA and PT; mIU/ml for HBsAg. aHIV-unexposed: HIV-uninfected children born to HIV-uninfected mothers; bART-Immed: HIV-infected children with CD4+ ≥25% at enrolment who were initiated on ART at enrolment; c*P* value: HIV-unexposed vs. ART-Immed; dART-Def: HIV-infected children with CD4+ ≥25% at enrolment randomized to deferred ART; e*P* value: HIV-unexposed vs. ART-Def; f*P* value: ART-Immed vs. ART-Def; gHEU: HIV-uninfected children born to HIV-infected mothers; h*P* value: HIV-unexposed vs. HEU; iFold-change: Fold-change in GMC between pre-booster and post-booster; jFold-change: Fold-change in GMC between post-booster and 24 months of age; k5 months: results of primary vaccination and have been published in Simani et al 2014 [[1](#_ENREF_1)]; lFold-change: Fold-change in GMC between 5 months and 15-18 months of age; mFold-change: Fold-change in GMC between 15-18 months and 24 months of age.

Explanatory notes:

Geometric mean concentration: All p-values were calculated by linear regression and adjusted for age, gender, race, study center, pre-booster antibody concentration (for post-booster and 24 months time-point) and CD4+ cell percentage in HIV-infected children.

Supplementary Table 4. Percentage of children with sero-protective antibody titers at pre-booster, post-booster and at 24 months of age

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Antibody | Threshold | Time-point | HIV-unexposeda  N=107 | ART-Immedb  N=146 | p-valuec | ART-Defd  N=61 | p-valuee | p-valuef | HEUg  N=114 | p-valueh |
| TT | ≥0.01 | Pre-booster: n/N; % (95% CI) | 107/107; 100  (97-100) | 145/146; 99  (96-100) | *0.39* | 61/61; 100  (94-100) | NE | *0.52* | 114/114; 100  (97-100) | NEi |
| Post-booster: n/N; % (95% CI) | 100/100; 100  (96 -100) | 135/135; 100  (97-100) | NE | 52/52; 100  (93-100) | NE | NE | 103/103; 100  (96-100) | NE |
| 24 months: n/N; % (95% CI) | 97/97; 100  (96-100) | 122/122; 100  (97-100) | NE | 48/50; 96  (87-99) | *0.05* | *0.03* | 97/97; 100  (96-100) | NE |
| ≥0.1 | Pre-booster: n/N; % (95% CI) | 85/107; 79  (71-86) | 72/146; 49  (41-57) | <0.001 | 26/61; 43  (31-55) | <0.001 | 0.38 | 90/114; 79  (71-85) | 0.63 |
| Post-booster: n/N; % (95% CI) | 100/100; 100  (96-100) | 135/135; 100  (97-100) | NE | 52/52; 100  (93-100) | NE | NE | 103/103; 100  (96-100) | NE |
| 24 months: n/N; % (95% CI) | 97/97; 100  (96-100) | 122/122; 100  (97-100) | NE | 36/50; 72  (58-83) | *<0.001* | *<0.001* | 95/97; 98  (93-99) | *0.16* |
| ≥1 | Pre-booster: n/N; % (95% CI) | 0/107; 0 | 1/146; 0.7  (0.1-4) | *0.39* | 1/61; 2  (0.3-9) | *0.18* | 0.47 | 1/114; 0.9  (0.2-5) | *0.33* |
| Post-booster: n/N; % (95% CI) | 100/100; 100  (96-100) | 130/135; 96  (92-98) | *0.05* | 44/52; 85  (73-92) | *<0.001* | 0.01 | 103/103; 100  (96-100) | NE |
| 24 months: n/N; % (95% CI) | 74/97; 76  (67-84) | 44/122; 36  (28-45) | <0.001 | 7/50; 14  (7-26) | <0.001 | 0.01 | 64/97; 66  (56-75) | 0.05 |
| DT | ≥0.01 | Pre-booster: n/N; % (95% CI) | 107/107; 100  (97-100) | 146/146; 100  (97-100) | NE | 61/61; 100  (94-100) | NE | NE | 105/114; 92.  (86-96) | *0.003* |
| Post-booster: n/N; % (95% CI) | 100/100; 100  (96-100) | 135/135; 100  (97-100) | NE | 52/52; 100  (93-100) | NE | NE | 103/103; 100  (96-100) | NE |
| 24 months: n/N; % (95% CI) | 97/97; 100  (96-100) | 122/122; 100  (97-100) | NE | 50/50; 100  (93-100) | NE | NE | 97/97; 100  (96-100) | NE |
| ≥0.1 | Pre-booster: n/N; % (95% CI) | 41/107; 38  (30-48) | 79/146; 54  (46-62) | 0.001 | 35/61; 57  (45-69) | 0.02 | 0.95 | 61/114; 54  (44-62) | 0.03 |
| Post-booster: n/N; % (95% CI) | 100/100; 100  (96-100) | 135/135; 100  (97-100) | NE | 52/52; 100  (93-100) | NE | NE | 103/103; 100  (96-100) | NE |
| 24 months: n/N; % (95% CI) | 96/97; 99  (94-100) | 121/122; 99  (96-100) | 0.76 | 40/50; 80  (67-89) | 0.02 | 0.004 | 95/97; 98  (93-99) | 0.49 |
| ≥1 | Pre-booster: n/N; % (95% CI) | 0/107; 0 | 0/146; 0 | NE | 0/61; 0 | NE | NE | 0/114; 0 | NE |
| Post-booster: n/N; % (95% CI) | 99/100; 99  (95-100) | 125/135; 93  (87-96) | 0.08 | 44/52; 85  (73-92) | 0.02 | 0.14 | 100/103; 97  (92-99) | 0.45 |
| 24 months: n/N; % (95% CI) | 31/97; 32  (24-42) | 16/122; 13  (8-20) | 0.001 | 1/50; 2  (0.3-1.0) | 0.003 | 0.03 | 26/97; 27  (19-36) | 0.40 |
| FHA | ≥4 fold increasej | Post-booster: n/N; % (95% CI) | 91/100; 91  (84-95) | 116/131; 89  (82-93) | 0.75 | 45/50; 90  (79-96) | 0.99 | 0.69 | 100/103; 97  (92-99) | 0.06 |
| PT | ≥4 fold increase | Post-booster: n/N; % (95% CI) | 99/100; 99  (95-100) | 126/131; 96  (91-98) | 0.31 | 45/50; 90  (79-96 | 0.10 | 0.19 | 102/103; 99  (95-100) | 0.88 |
| HepB | ≥10 | 15 -18 months: n/N; % (95% CI) | 107/107; 100  (97-100) | 146/146; 100  (97-100) | NE | 61/61; 100  (94-100) | NE | NE | 114/144; 100  (97-100) | NE |
| 24 months: n/N; % (95% CI) | 97/97; 100  (96-100) | 122/122; 100  (97-100) | NE | 36/50; 72  (58-83) | *<0.001* | *<0.001* | 97/97; 100  (96-100) | NE |
| ≥100 | 15-18 months: n/N; % (95% CI) | 107/107; 100  (97-100) | 142/146; 97  (93-99) | *0.08* | 61/61; 100  (94-100) | NE | *0.19* | 107/114; 94  (88-97) | *0.01* |
| 24 months: n/N; % (95% CI) | 93/97; 96  (90-98) | 112/122; 92  (86-96) | 0.28 | 25/50; 50  (37-63) | <0.001 | <0.001 | 89/97; 92  (85-96) | 0.17 |

Footnote: Percentage of participants with concentration above threshold (95% confidence interval) Units are IU/ml for TT, DT, FHA and PT; mIU/ml for HBsAg. aHIV-unexposed: HIV-uninfected children born to HIV-uninfected mothers; bART-Immed: HIV-infected children with CD4+ ≥25% at enrolment who were initiated on ART at enrolment; cp-value: HIV-unexposed vs. ART-Immed; dART-Def: HIV-infected children with CD4+ ≥25% at enrolment randomized to deferred ART; ep-value: HIV-unexposed vs. ART-Def; fp-value: ART-Immed vs. ART-Def; gHEU: HIV-uninfected children born to HIV-infected mothers; hp-value: HIV-unexposed vs. HEU; iNE: not evaluable; j≥4 fold increase: sero-conversion rate, children showing 4 fold increase in antibody concentration from pre-booster to post-booster dose.

Explanatory notes: Percentage participants: p-values were either calculated by logistic regression and adjusted for age, gender, race, study center, pre-booster antibody concentration (for post-booster and 24 months time-point) and CD4+ cell percentage in HIV-infected children; or by Pearson’s chi-square test for values in italics.