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Atazanavir in Pregnancy



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Atazanavir (ATV) in Pregnancy



- * Not Licensed for use in pregnancy
- * Few published data on use in pregnancy
 - * Largest cohort 40 women (2009)¹

¹Conradie F et al. The safety efficacy and steady state pharmacokinetics of atazanavir/ritonavir once daily when given in combination with twice daily AZT/3TC during pregnancy: results of study AI424182. Fifth International AIDS Society Conference on HIV pathogenesis, Treatment and Prevention, 19–22 July 2009, Cape Town, South Africa.

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Methods



- * Retrospective review ATV exposed pregnancies
 - * 155 pregnancies in 145 women
 - * 12 London sites: December 2004 - present
 - * Pregnancies achieving $\geq 12/40$ included
- * Data collected regarding:
 - * reasons for commencement and cessation of use
 - * tolerability and toxicity
 - * gestational age at delivery
 - * birth and infant outcomes

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Baseline Characteristics

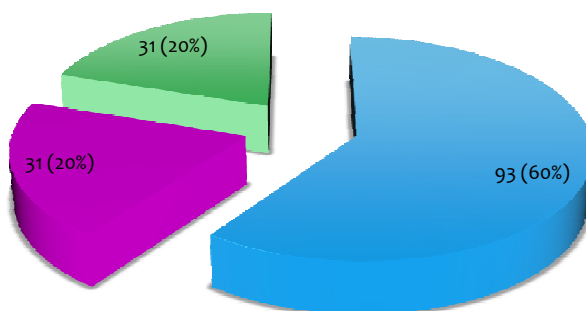


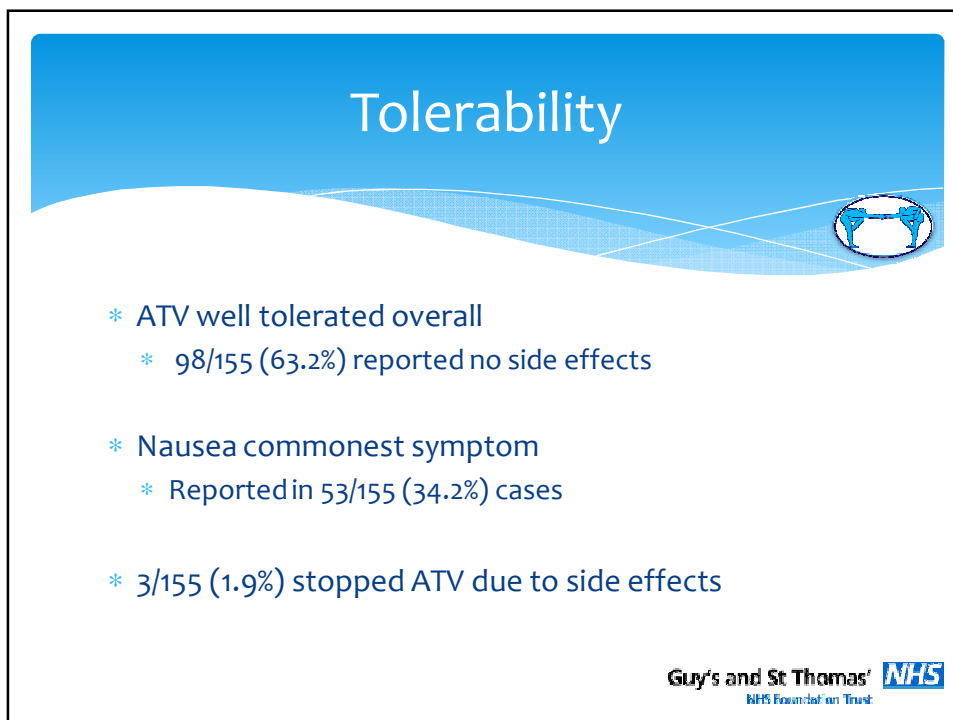
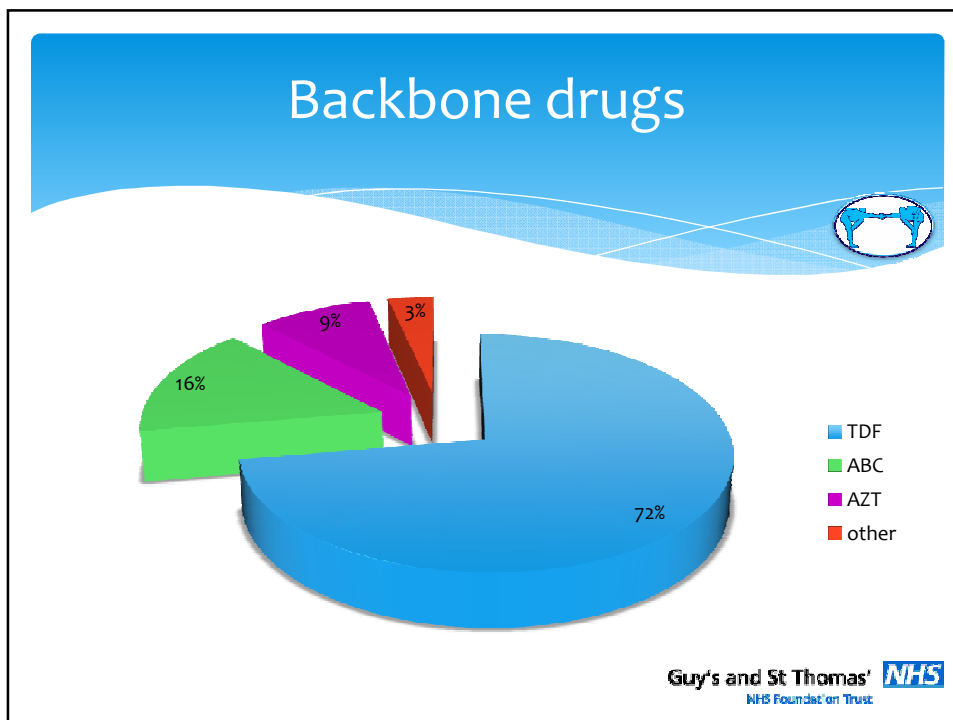
Black African	n=118	76.1%
Median Age (years)	32	15- 47
IVDU	5	3.2%
Newly diagnosed this pregnancy	n=15	9.7%
Hep B co-infection	6	3.9%
Hep C co-infection	2	1.3%
On HAART at conception	n=105	68%

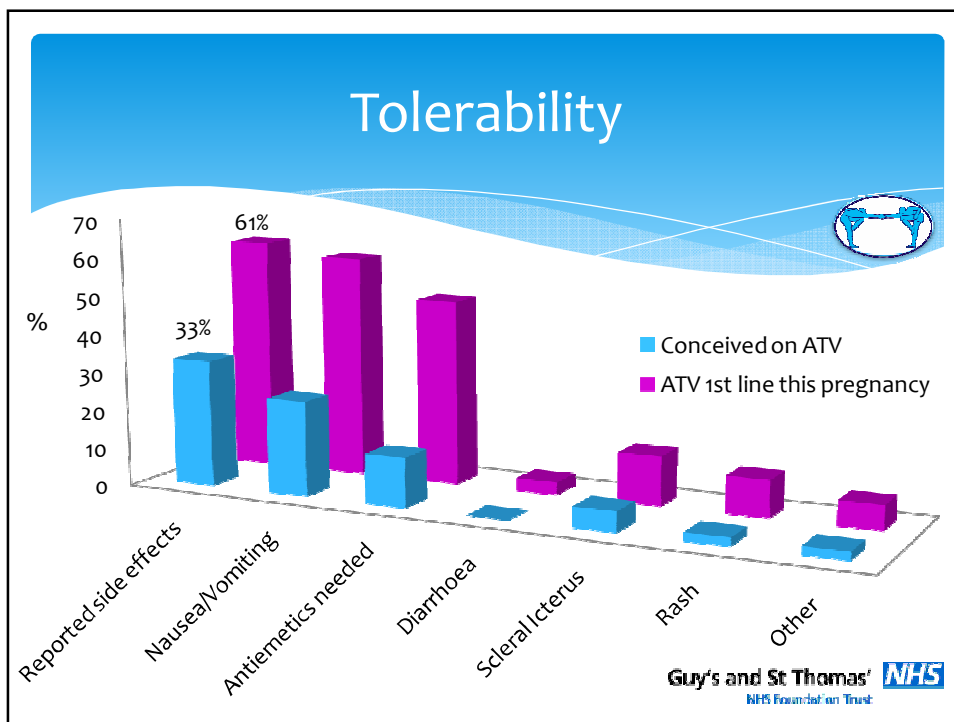
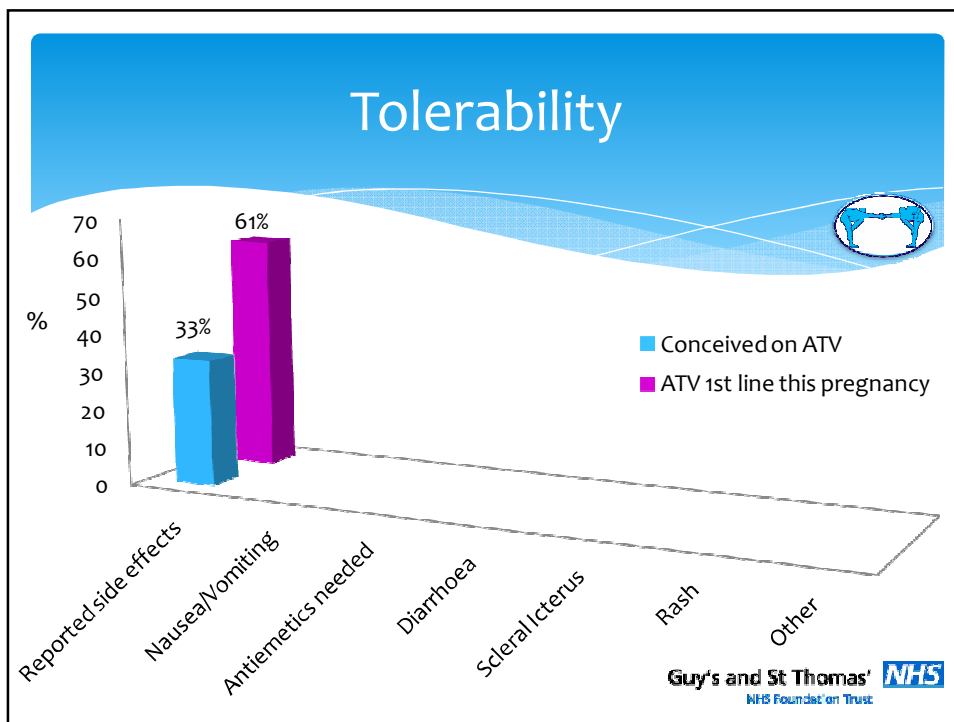
Atazanavir use in pregnancy



- Conceived on ATV
- Commenced ATV first line in pregnancy
- Converted to ATV from another HAART regimen in pregnancy







Patients switching to atazanavir in pregnancy for tolerability issues



- * 21 switched to ATV due to pre-existing GI side effects
- * 20/21(95.2%) from a PI based regimen
- * Symptoms improved in 19/21 (90.5%)
- * 1 stopped ATV with persistent nausea

Hepatotoxicity



- * Low overall incidence of hepatotoxicity
- * 9 (5.8%) developed G1-4 ↑ transaminase
- * 5 converted to ATV with pre-existing hepatotoxicity
 - * 1 from NVP; 4 from LPV/r
- * LFTs resolved in 3
- * 2 had persistent hepatotoxicity
 - * ATV stopped in both cases

Therapeutic Drug Monitoring

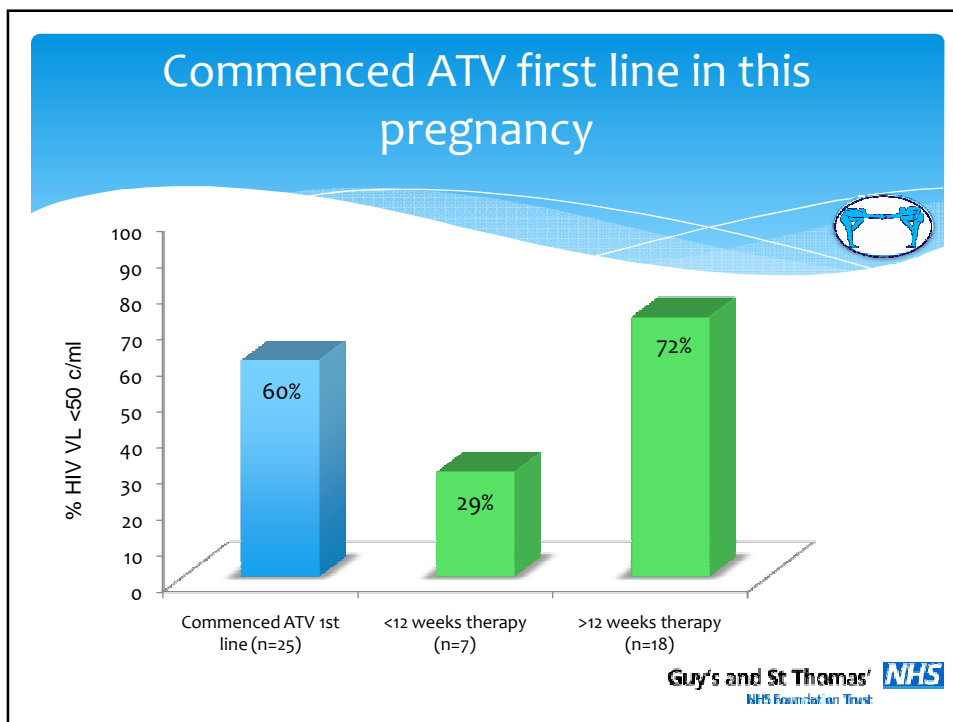
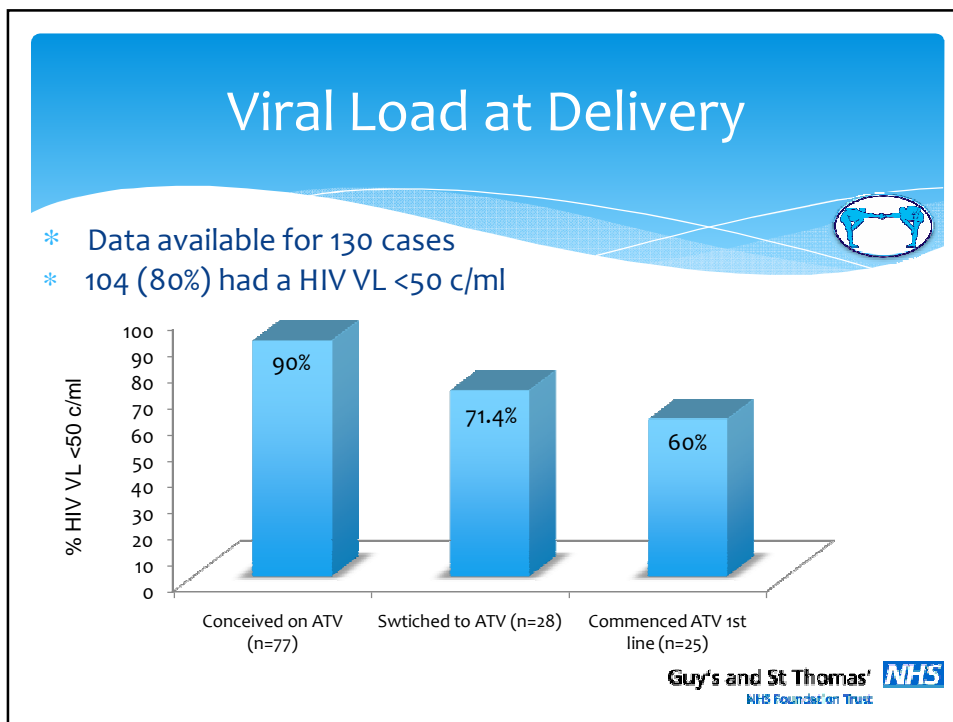


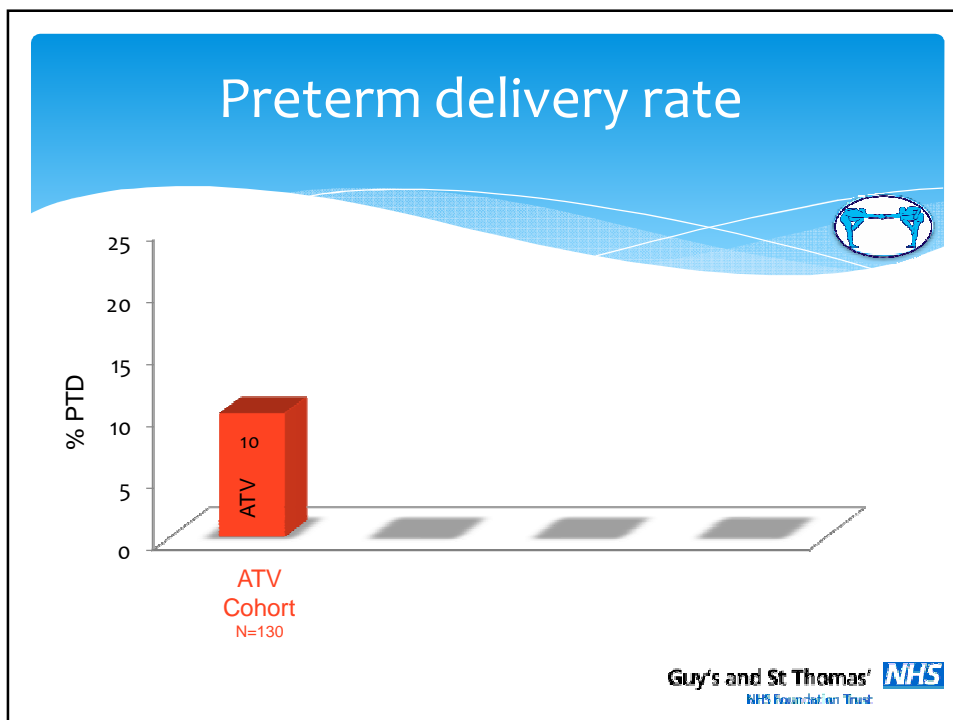
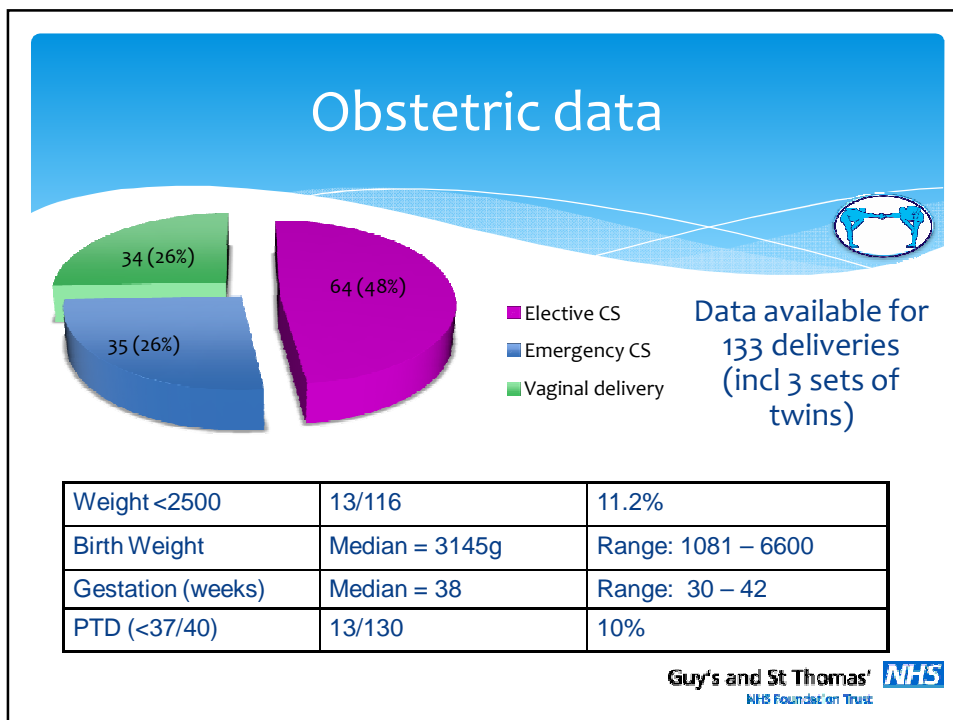
- * 17 had routine 3rd trimester TDM
 - * Median trough 811 ng/ml (304-2210)
- * 11 had 3rd trimester TDM for ↑VL
 - * median 247 ng/ml(0-1393)
 - * 4 had levels <150 ng/ml
 - * ? poor adherence in 3/4

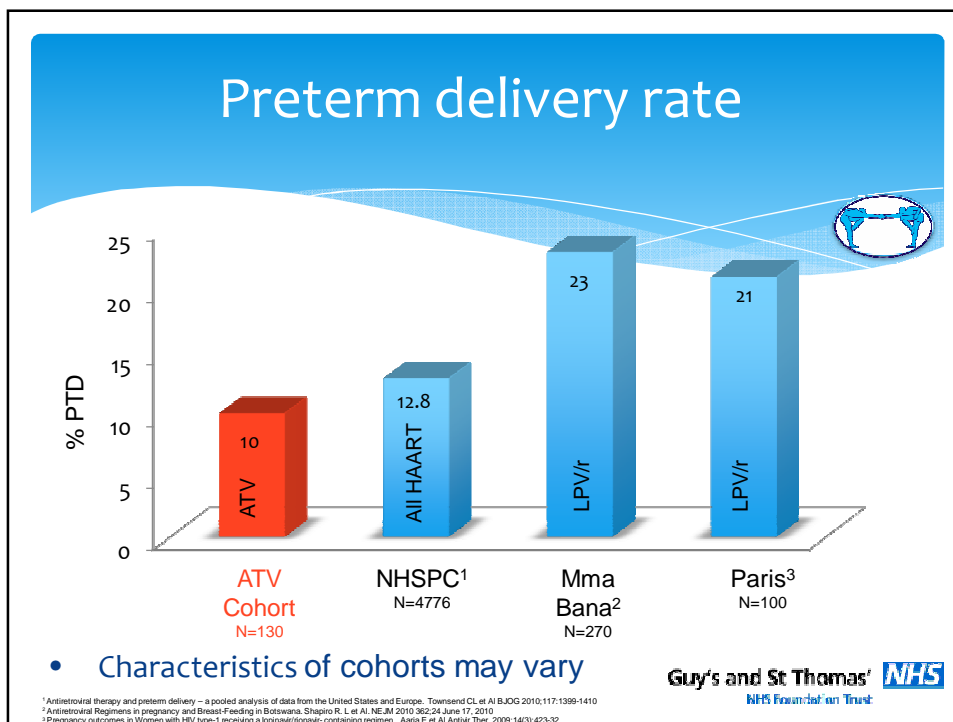
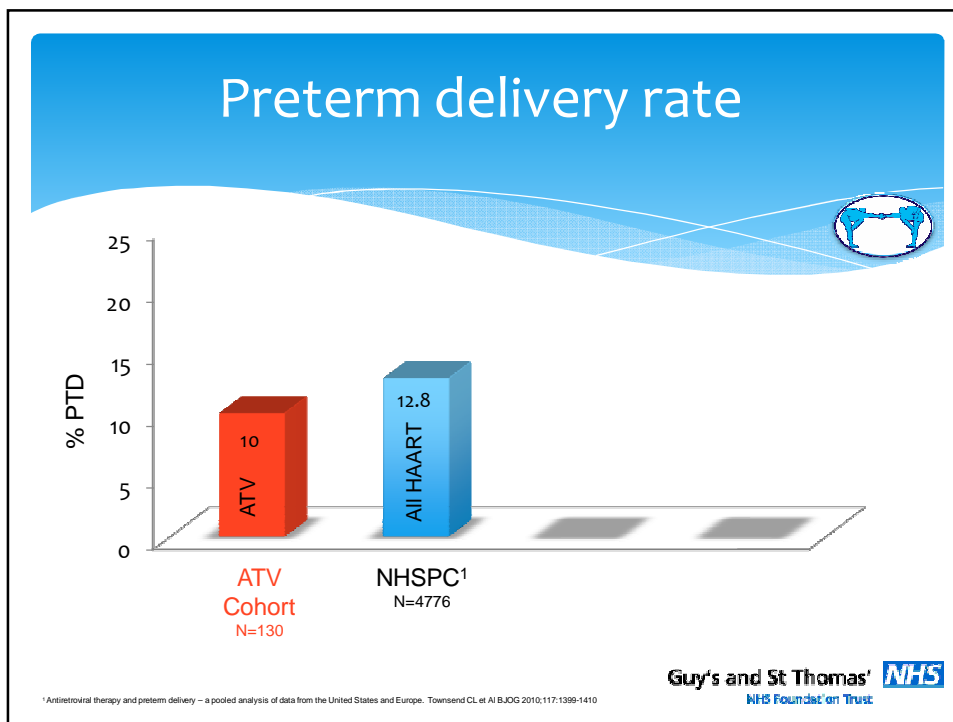
Viral Load at Delivery



- * Data available for 130 cases
- * 104 (80%) had a HIV VL <50 c/ml







Infant safety data




- * 94 infants had neonatal bilirubin measured
 - * Median 71 $\mu\text{mol/L}$ (3-258)
 - * 3 neonates had phototherapy
 - * 1 polycythaemic (Bili 258 $\mu\text{mol/L}$)
 - * 1 infant haemolytic anaemia (Bili 109 $\mu\text{mol/L}$)
 - * 1 no other cause (Bili 194 $\mu\text{mol/L}$)
- * 1 congenital cardiac abnormality

Vertical Transmission



- * 1/155 (0.65%)
- * Mother had history of poor adherence
- * Neonatal proviral DNA positive
- * *In utero* transmission


Conclusions




- * Atazanavir is well tolerated in pregnancy
- * Low toxicity and discontinuation rates
- * Good tolerability and efficacy in patients conceiving on ATV
- * Reasonable 'switch' option in pregnancy for toxicity or tolerability issues
- * Infant safety data are reassuring

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Conclusions



- * More data needed around viral load suppression in patients starting ATV 1st line in pregnancy
- * Preterm delivery rate is the most favourable reported to date for a PI based regimen in pregnancy but more data are required

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