Audit, Information Analysis Unit

National Study of HIV
in Pregnancy and Childhood

Perinatal transmission of HIV in England 2002-2005

Executive Summary

October 2007

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1. Executive Summary

Reduction of transmission of HIV perinatally from mothers to their infants is one of the resounding success stories of the epidemic to date. With appropriate management and support for the women and adequate health care resources, the transmission rate has been cut from 25% or higher to about 1%. Despite a decline in the proportion of children being infected, the actual numbers each year are relatively stable because of the steady increase in the number of HIV infected women giving birth. Across the UK more than 30 infants are still being infected annually, and each carries a substantial human and economic cost.

This audit was devised to explore the circumstances surrounding recent cases of mother-to-child transmission (MTCT) and to recommend changes that might result in more timely diagnosis or improved management to reduce future transmission rates.

The project has been a collaborative undertaking between the National Study of HIV in Pregnancy and Childhood (NSHPC), the Audit Information and Analysis Unit for Specialised Services (AIAU), and the Children's HIV Association of the UK and Ireland (CHIVA). For pragmatic reasons, the audit was confined to children who were born in England during the four year period between 1st January 2002 and 31st December 2005 and who were reported to the NSHPC as HIV infected by 1st April 2006.

Altogether 87 children were identified as fulfilling these conditions. Subsequently, a further 24 children born during the study period were diagnosed and reported by March 2007, most of whom were born to undiagnosed women in 2004/5. It is likely that a small number of infected children remain undiagnosed at the time of finalising this report.

Respondents who had notified an infected infant were asked to complete a comprehensive audit form covering relevant aspects of antenatal, intrapartum and postnatal care. Forms were returned for 93% of the cases. Additional information was obtained from surveillance data routinely collected by the NSHPC and from the UK HIV Drug Resistance database held by the MRC Clinical Trials Unit.

The standards used were the British HIV Association (BHIVA) pregnancy guidelines (2001 and 2005, as appropriate), and Department of Health (DH) Screening for Infectious Diseases in Pregnancy Standards to Support UK Antenatal Screening Programme (2003).

It is important to bear in mind that the audit was not designed to ask what went right in the 3,600 pregnancies that resulted in the birth of an uninfected baby in England during the study period. The audit team acknowledges the limitation of the audit design which does not allow comparison with these 'successful' cases.

Of the 87 infected infants identified, 33 were born to women whose HIV infection was diagnosed before or within 48 hours of delivery. In this group, all possible actions that might have reduced the risk of transmission were investigated. Failure of communication, between health care professionals and the mother, and between themselves, and failure to ascertain or act upon suboptimal virological responses were identified as issues. An emerging theme was the problem of preterm delivery foreshortening the time for antiretroviral therapy to be administered during pregnancy; in some cases, the obstetric history would have identified the risk of premature delivery, highlighting the need for individualised management.

For the 54 infants born to undiagnosed women, it was frequently difficult to obtain full details of the antenatal and intrapartum management. Amongst this group, at least 20% were born following maternal seroconversion during pregnancy. Health economic data are needed to consider whether a second HIV test should be offered in the 3rd trimester. Partner testing was beyond the remit of this audit, but in view of the evidence that sexual transmission of HIV is occurring in pregnancy, this should be addressed in future guidelines and audits.

All too often, adverse social circumstances mitigated against the delivery of optimal care. Even so, there were opportunities for intervention perinatally that were missed. In a few cases, care was not accessed because health care professionals or the women themselves were unclear as to whether HIV infection in pregnancy constitutes an emergency condition and is eligible for free NHS treatment. Given the audit evidence of transmission of HIV to the infant under these circumstances, we have recommended that this policy should be clarified nationally, rather than left to the decision of individual NHS Hospital Trusts.

No cases were identified in which transmission occurred following optimal care and with an undetectable maternal viral load at delivery. The only transmitting mother who was documented as having an undetectable viral load at delivery had travelled abroad during pregnancy and had malaria. Her infant had a positive PCR test on day 1 consistent with intra-uterine transmission, most probably in association with the episode of malaria which is a recognised risk factor for transmission.

To date 11 of the 87 children are known to have died. Seven of the 54 whose mothers were not diagnosed died within a year of birth of AIDS related conditions, and another two died during their second year of life; 60% of the survivors in this group have experienced at least one AIDS defining illness. Two deaths have been reported from the diagnosed group, and 6 of the 31 survivors have had an AIDS defining illness. Thus the mortality rates by the age of 2 years were 6% in the diagnosed group, and 17% in the undiagnosed group. Failing to make the diagnosis in pregnancy is clearly detrimental to the outcome for the child.

The recommendations have been ordered chronologically, following the care pathway for a pregnant woman. Some of these are already in current published guidelines, and are restated in light of the audit findings. Other recommendations have been made in direct response to evidence from the audit as documented in the body of the report. These recommendations should be considered as an entire package by members of the multi-disciplinary team responsible for antenatal and perinatal services. Particularly important points have been highlighted, but in most cases of transmission more than one factor was identified. Nursing and medical managers must ensure that staff providing care are fully aware of their responsibilities. Those involved in the provision and funding of antenatal and perinatal services should be attentive to the possible financial and legal risks related to avoidable vertical transmission.

Footnote:
The London Multi-Centre Research Ethics Committee granted ethics approval for the study. The NSHPC is funded through the Health Protection Agency, with additional departmental support from the Institute of Child Health. The AIAU, funded by PCTs across London, Kent, Surrey, Sussex, Essex, Beds and Herts, provided strategic support and a project coordinator.

2. Recommendations

Section numbers indicate where each recommendation can be found in the Full Report

Antenatal care	Section in full report	To be in place, and reviewed within:
1. **All pregnant women should be recommended an HIV test at the time of booking; any woman who declines the test at first offer should be recommended it on at least one more occasion, preferably during the second trimester and by a member of the team with specialist training.**	**13.1 14.3**	**1 year**
2. **Positive test results should normally be given in person within 2 weeks of testing.**	**13.1 14.3**	**1 year**
3. **For women booking or being tested after 20 weeks, blood samples should be marked urgent for rapid testing. This is particularly important if there is an increased likelihood of preterm labour (see Recommendation 11, below). Women tested at 28 weeks or later should be offered point of care testing, or rapid testing within 24 hours.**	**13.1**	**1 year**
4. **Dates and details of test discussions, who these involved, decisions, samples taken, and when results were available and were given, should be recorded.**	**13.1**	**1 year**
5. **Local protocols should ensure that there is a clear line of designated responsibility for communicating positive results and following up late results; these should make provision for staff absence for any reason.**	**13.1 14.3**	**1 year**
6. HIV positive women should have an STI screen as early as possible during pregnancy and this should be repeated at around 28 weeks.	13.2 13.3	2 years
7. HIV positive pregnant women should be screened for Hepatitis C.	13.2 13.3	2 years
8. All antenatal notes (including screening results) for any woman transferred from one unit to another, should be forwarded to the appropriate clinical lead midwife. If any screening test results are missing, the relevant test should be recommended to the woman at the new unit.	13.2 13.3	2 years
9. Amniocentesis should normally only be carried out after a women's HIV status has been established.	14.3	2 years
10. CD4 and viral load results should normally be available within 2 weeks of the woman being informed of her diagnosis; however, if delivery is imminent, treatment decisions should not be delayed pending these results.	13.6	2 years
11. Women's individual circumstances should be considered so that ART can be started at an appropriate time, depending on gestation at diagnosis, previous obstetric history, and other relevant considerations. For example a woman who has previously delivered at 28 weeks ideally needs to be on ART by 20 weeks gestation.	13.6	2 years

12. Resistance testing should be undertaken on all HIV infected women and repeated according to current guidelines. For women presenting at 20 weeks or later, samples for resistance testing should be fast-tracked and ideally should be available within 2 weeks, and certainly within 4 weeks. Empiric treatment should not be delayed pending resistance results for women who have indications for starting ART immediately.	13.6	2 years
13. HIV positive women presenting on complex therapies or with co-morbidities or STIs require urgent individualised treatment and close monitoring, including therapeutic drug monitoring and adherence support as necessary.	13.2 13.3 13.6	2 years
14. If the maternal viral load response to HAART is sub-optimal (less than 1 log drop in 2 weeks, or still detectable at 36 weeks gestation), appropriate action should be taken and expert advice sought if necessary.	13.6	2 years
15. **Adverse social circumstances and complex problems must be properly documented. Women identified with complex social needs require early multidisciplinary discussion that includes a member of the paediatric team, and appropriate referral and support. Duty of confidentiality should not compromise duty of care.**	**13.5**	**1 year**
16. Early involvement of Social Services is essential if there are serious concerns about a woman's mental health, or if potential child protection issues are identified.	13.5	2 years

Around the time of delivery	**Section in full report**	**To be in place, and reviewed within:**
17. All staff who need to know about a woman's HIV status in order to ensure appropriate care of both woman and infant should have access to the relevant information. Labour wards and neonatal units should be aware in advance of diagnosed women who are due to deliver, and have prompt access to each woman's birth plan. Local protocols should identify a designated staff lead to ensure this. If HIV results are recorded electronically, labour ward staff should also check the status of all women presenting in labour.	13.1 13.7	2 years
18. **Rapid/same day tests should be recommended to women who present in labour with unknown HIV status, including those who arrive unbooked and those who previously declined an HIV test.**	**13.1 14.3**	**1 year**
19. If an HIV infected woman was diagnosed but declined further care, labour ward staff should be informed so that labour and delivery can be managed appropriately and prophylaxis provided for the infant. Local protocols should set out how to achieve this.	13.1	2 years
20. Current screening guidelines on Hepatitis B and syphilis screening for all women presenting unbooked and in labour should be adhered to, using appropriate rapid methods.	13.2 13.3	2 years
21. BHIVA guidelines for the active management of all modes of delivery should be followed.	13.7	2 years
22. All infected women should continue taking ART during labour; in most cases this will be their usual oral regimen according to their established daily schedule. Where monotherapy with ZDV (AZT) has been selected, an intravenous infusion should be administered during labour. Units should ensure intravenous and oral drugs are readily available.	13.7	2 years

The postnatal / neonatal period	Section in full report	To be in place, and reviewed within:
23. **Every effort should be made to ensure that there is no delay in starting neonatal ART. The timing of initiation of ART should be recorded, along with the reason for any delay. In any case where there is an increased risk of transmission triple therapy should be considered.**	**13.8**	**1 year**
24. In cases where the birth plan had been for single dose infant prophylaxis, but problems arise during delivery that increase the risk of transmission, there should be early consultation with the paediatric team to decide whether triple therapy for the infant is required.	13.8	2 years
25. Infant HIV diagnostic samples should be sent in accordance with BHIVA guidelines, minimally at day 1 and 6 weeks of life. Dates, tests and results should be recorded; results should be reviewed within two weeks. This is to clarify the likely timing of infection and to enable early modification of treatment if a child is infected.	13.8	2 years
26. Educational and social support to enable every mother to formula feed her infant safely should be provided.	13.8	2 years
27. As with other routine antenatal serology, maternal HIV status should be recorded in neonatal notes. Prompt consideration should be given to testing any newborn infant whose mother's HIV status is unknown (and especially if she repeatedly declined the test).	14.3	2 years

Other issues	Section in full report	To be in place, and reviewed within:
28. **When an infant / young child is diagnosed with HIV, the diagnosing paediatrician should seek permission from the mother to inform the relevant obstetric unit that they delivered an infected infant to an undiagnosed woman, in order that procedures can be reviewed and revised.**	**14.3**	**1 year**
29. **Every Trust that provides care for HIV infected pregnant women should have a designated HIV lead for obstetrics and for paediatrics.**	**14.3**	**1 year**
30. If a mother is identified on antenatal screening as HIV infected, every effort should be made to test her partner and any children.	14.3	2 years
31. **At the next policy review, the DH should consider classifying HIV prophylaxis for prevention of mother to child transmission, and appropriate support in pregnancy and for her infant, as emergency care. As such, care should be free, regardless of immigration, asylum or residence status.**	**13.5**	

3. Action plan for implementation of recommendations

Obstetric and paediatric units should review this document and develop an action plan to implement recommendations pertinent to their unit. Local recommendations should be presented to all relevant departments.

Some of the recommendations are already in current published guidelines, others have been made in direct response to evidence from the audit. High priority recommendations should be reviewed by obstetric and paediatric departments within one year of the audit report circulation.

Commissioners need to ensure that the recommendations are met by the units in their region.

The AIAU will also review, with trusts and commissioners in the South East of England, how project recommendations have been considered a year after circulation of the audit report.

4. Acknowledgements

The project team would like to acknowledge the support of the Audit, Information and Analysis Unit, and to thank everyone who participated in this audit, particularly those who completed the proformas in obstetric and paediatric units (see list of Key Contributors, p.10), and the clinicians, commissioners and others who gave their expert advice and comments at all stages. It would not have been possible to carry out the audit without the ongoing support and involvement of the hundreds of health service staff who provide surveillance data to the National Study of HIV in Pregnancy and Childhood on a regular basis – their contribution is also much appreciated.

We would also like to thank:

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- The Children's HIV Association (CHIVA)
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Non-participation

Audit forms relating to 4 cases were not returned from 4 Trusts.

In one instance, case notes were not available as an enquiry was on-going (Yorkshire & Humber region).

Two respondents did not return the audit form despite reminders:
- Central Manchester and Manchester Children's University Hospital NHS Trust
- New Cross Hospital. Royal Wolverhampton Hospitals NHS Trust

One respondent from Leeds General Infirmary, Leeds Teaching Hospitals Trust declined to complete the audit form as they 'had no time to participate'.

Blank audit forms were returned by 2 respondents from:
- Guy's and St Thomas' NHS Foundation Trust
- Ashford & St Peter's Trust

Another audit form was completed but not received; summary details were subsequently provided.

Information previously provided to the NSHPC through the routine surveillance systems has been included in this report where appropriate, including data for these cases.

7. References

BHIVA pregnancy guidelines (2001 and 2005)
British HIV Association. Guidelines for the Management of HIV infection in Pregnant Women and the Prevention of Mother-to-Child Transmission of HIV. March 2005. Available at: www.bhiva.org. (2001 guidelines also)

Department of Health. Screening for infectious diseases in pregnancy. Standards to support the UK antenatal screening programme (August 2003) Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4050934

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