

Ms A, Midwife

Public Hospital

**A Report by the
Health and Disability Commissioner**

(Case 04HDC14171)



Health and Disability Commissioner
Te Toihamu Hamora, Hauātanga

Introduction

The issue of HIV screening in pregnancy is vexed and controversial, as noted in the National Health Committee's report: "HIV Screening in Pregnancy: A Report to the New Zealand Minister of Health" (October 2004). This complaint highlights the very serious outcome when HIV in pregnancy is not identified and the risk of transmission to the baby is not minimised.

Parties involved

Infectious diseases physician	Complainant
Ms X	Consumer, Master Y's mother
Master Y	Consumer
Mr X	Master Y's father
Ms A	Provider, midwife
Public Hospital	Provider
Dr B	General practitioner
Dr C	Obstetric registrar
Dr D	Haematologist
Dr E	Gynaecology house officer
Dr F	Gynaecologist
Dr G	Paediatrician
Dr H	Clinical Leader, Public Hospital

Complaint

On 23 August 2004 an infectious diseases physician (the complainant) made a complaint to the Health and Disability Commissioner (HDC) on behalf of Mr X and Ms X about the following matters:

- failure to undertake an HIV test in pregnancy after recognising that Ms X was at risk for HIV
- inadequate follow-up of markedly abnormal blood results that led Dr D (haematologist) to recommend a review of Ms X's clinical situation because of a possible inflammatory or infective process.

The complainant forwarded to HDC copies of relevant correspondence regarding Master Y, and the Ministry of Health's circular letter to health professionals: "HIV in pregnancy: Risk screening guidelines and information for health professionals" (February 1997) (the guidelines). In a letter to the complainant dated 27 July 2004, ACC indicated that the guidelines were not circulated to midwives, and that this was confirmed by a professional advisor of the New Zealand College of Midwives. The complainant disputes this, and

submits that the guidelines specifically stated that the document was circulated to health professionals and that it was prepared in conjunction with the New Zealand College of Midwives and the College of Nurses Aotearoa. Furthermore, the complainant states that midwives were well aware of the issue of HIV in the late 1990s and early 2000 and there has been a major debate and difference of opinion among midwives about the issue of HIV.

The complainant also referred to a copy of HDC's letter to the National Health Committee, dated 31 July 2002, in relation to whether there is a legal duty to routinely offer an HIV test to pregnant women. In this letter, the Commissioner noted that the guidelines were under review and that they are not generally complied with. However, the Commissioner stated that it appears that there is no dispute about the duty to assess a pregnant woman's HIV risk, and inform her of the risk of HIV and HIV transmission to the baby.

On 7 October 2004 the complainant advised HDC that he was waiting for the release of the National Health Committee's report "HIV Screening in Pregnancy: A Report to the New Zealand Minister of Health" (October 2004) and hoping that the report would address his concerns about HIV screening in pregnancy in New Zealand. The report was launched the following week. On 13 October the complainant informed HDC that he was disappointed with the National Health Committee's report and wished to proceed vigorously with the complaint, and confirmed that Mr X and Ms X supported it. The complainant explained that he had written to the National Health Committee, and stated: "The evidence is overwhelming that universal opt-out works and is easy to implement. Selective screening doesn't work."

Factual background

Mr X and Ms X are the parents of Master Y, who is currently five years old. Ms X is a Thai national who has been a resident of New Zealand since the late 1990s. In 1995 Ms X had a full-term normal vaginal delivery in Thailand and gave birth to a child with a Thai father.

Obstetric care

In early 1999 Ms X became pregnant again in New Zealand. Her general practitioner, Dr B, referred her to a public hospital for antenatal care. Dr B performed antenatal blood tests before the referral, including a full blood count; syphilis, hepatitis B, and rubella serology; and blood group antibody screening. The full blood count showed a mild neutropenia (low neutrophil count) with a comment on the report that this needed follow-up. There was no record in the referral letter that HIV testing was performed or discussed with Ms X.

Ms A attended Ms X as a community midwife employed by the hospital. On 22 April 1999 Ms A booked Ms X, who was 14 weeks and three days pregnant. It was noted that Ms X was a recent immigrant from Thailand and it was recorded that she did not need an interpreter. Repeat booking antenatal blood tests were performed and revealed a normocytic normochromic anaemia (low red blood cell count) and again, a mild neutropenia. On 28 April the anaemia was noted in the antenatal record and a prescription for iron was given. Ms X then had routine antenatal care with midwifery review every three weeks.

On 28 July 1999 Ms X was seen by Dr C, obstetric registrar, and noted to have an ongoing anaemia. Dr C recommended twice daily iron supplementation and repeating the blood tests in four weeks' time. Ms X then had fortnightly review.

On 25 August, following further blood tests, Dr D, haematologist, reported a persisting normocytic normochromic anaemia along with an elevated ESR (erythrocyte sedimentation rate) and left shift in granulocytic cells. Dr D noted the lack of response of the anaemia to iron therapy and commented that the anaemia was likely to be due to an underlying systemic illness from an inflammatory or infective process. He suggested performing iron studies and protein electrophoresis, and reviewing the clinical situation.

Ms A received Dr D's report dated 25 August and said she discussed the result with one of the obstetric registrars (whose name she cannot remember). Ms A ordered a number of investigations and wrote on Dr D's report: "1/9/99 Diagnostic form sent to do FBC [full blood count], Fe [iron] IBC [iron binding capacity], ferritin, B12, folate, liver group, creatinine, electrolytes, uric acid." The hospital has been unable to identify the obstetric registrar, and the discussion was not documented. Ms A is unable to remember the details of the discussion. There is no record in the clinical notes of Ms X being reviewed by clinic medical staff after repeat blood tests were performed.

Throughout the pregnancy, Ms X was noted to be generally well and essentially asymptomatic. An HIV test was not done. In late October 1999 Ms X was admitted to the hospital in labour after a spontaneous rupture of membranes at 11pm. She had an augmentation of labour with intravenous syntocinon (a hormone to stimulate contractions of the uterus). She developed a fever during labour, with a temperature reaching 37.8 degrees Celsius and was given two doses of intravenous amoxycillin (antibiotic). Ms X had a prolonged labour resulting in a Ventouse vaginal delivery of baby Y at 2.30pm the following day. The baby was delivered in good condition with Apgar scores of 9 and 10 and a normal clinical examination.

Postnatally, Ms X had a persistent fever. The on-call medical staff noted a raised temperature of 37.9 degrees Celsius and a systolic heart murmur. No source of infection was found on investigation and she was treated with intravenous Cefuroxime (antibiotic). Five days after her baby's birth, Ms X was discharged from hospital. The baby was breast-fed for 12 months.

Gynaecology care

At around the time Dr B referred Ms X to the hospital for antenatal care in 1999, he performed a cervical smear, which showed CIN 2/3 (cervical intraepithelial neoplasia). Ms X was referred to the colposcopy clinic at the hospital and attended on 7 April 1999. Dr E, gynaecology house officer, performed a colposcopy, which revealed an area of high-grade squamous intraepithelial abnormality of the cervix and a polypoid lesion on the cervix. A repeat colposcopy on 30 June 1999 did not reveal any high-grade lesions. On 17 January 2000 Dr F, gynaecologist, performed a postpartum colposcopy and the biopsied tissue suggested a low-grade lesion and chronic cervicitis. On 10 July 2000 Dr F's assessment showed a generally inflamed cervix; the smear showed atypical cells and the biopsy was consistent with HPV (human papilloma virus) and CIN 1. A plan was made for Ms X to have a further smear test in six months' time and a repeat colposcopy in 12 months' time.

Ms X did not attend these appointments. There is no record of HIV testing being discussed or offered at the consultations.

Diagnosis of HIV

In April 2000 Ms X developed a right retinal vein thrombosis. She was under regular review by an ophthalmologist. Retinal vein thrombosis is not a classic feature of HIV infection and an atypical condition in a person of Ms X's age. The ophthalmologist suggested that Ms X's general practitioner undertake further investigations, which included blood clotting tests. The ophthalmologist also noted that Ms X was from Thailand and suggested performing an HIV test. In May 2001 the first test for HIV was positive and the general practitioner contacted an infectious diseases physician.

Master Y's care

When Ms X was diagnosed with HIV infection, Master Y was tested and also found to be positive for HIV at age 18 months. Mr X was also tested and found to be positive for HIV. The infectious diseases physician referred Master Y to Dr G, paediatrician, for further care. On 25 June 2001 Dr G noted that according to the paediatric HIV classification, Master Y would fall within the N2 category of early signs and symptoms but evidence of moderate immune suppression. His CD4 count was very low (400×10^6 per litre or 60% of the total white cell count). On 26 November 2002 the infectious diseases physician noted that Master Y's life expectancy will be severely shortened because of his diagnosis of HIV with his immune system already significantly damaged. In a letter to ACC dated 14 April 2003, Dr G explained that Master Y has HIV infection with an AIDS defining opportunistic illness and that although it is unknown how long Master Y will survive, he will have a reduced life span.

Ministry of Health guidelines

The Ministry of Health's guidelines (February 1997) were prepared "to provide health professionals with current information and general guidelines on issues surrounding mother-to-child transmission of HIV". The guidelines sought to assist health professionals with ways of assessing and managing pregnant women, their partner(s), and children who are at risk for HIV transmission during pregnancy. The introduction to the guidelines indicates that the risk screening guidelines were "an interim approach with a focus on early screening and testing while data are being collected to determine if routine antenatal testing is appropriate or indeed desirable".

The guidelines (at pages 6 and 7) state: "Until such time as voluntary testing might be introduced as part of routine pregnancy care, it is recommended that as part of the antenatal discussion, the risk of HIV for both the woman and her partner(s) should be assessed and in cases where risk factors are identified or not clear, counselling and voluntary testing be offered." The guidelines suggest approaches for discussing the need for HIV testing and list a number of screening questions including: "Have you or your partner(s) ever had sexual contact with a person from an overseas country, particularly one where HIV/AIDS is common such as in Africa or Asia?" Furthermore, the guidelines (at page 9) state: "If possible at the first antenatal visit, women should be asked about risk behaviours for HIV."

Dr Karen Poutasi, Director-General of Health, advised HDC that the Ministry of Health does not have the original distribution list for the 1997 guidelines but is “quite certain that it would have been sent to all lead maternity carers, including midwives, and relevant professional bodies”. In addition, guidance is on the Ministry of Health website.

“Prescriber Update No. 13” published by the Therapeutic Section of the Ministry of Health (October 1996) also provided information to health professionals about the need to assess HIV infection risk in pregnant women.

Claim to ACC

On 26 November 2002 the infectious diseases physician made a claim to ACC on behalf of Mr X and Ms X for compensation following Master Y’s infection with HIV, allegedly as a result of a lack of screening for HIV. The infectious diseases physician claimed that if the HIV test had been undertaken, then it would almost certainly have prevented Master Y being born with HIV.

On 10 September 2003 ACC declined the claim. ACC obtained the following independent advice from an obstetrician and gynaecologist: “In the present climate of uncertainty, it would be difficult in this present case to lay blame at the door of a registered health professional or organisation. As there is no policy of routine testing of pregnant women and testing relies on the caregiver having sufficient suspicion that a patient is at risk of HIV, the claim must be declined.” ACC concluded that it is impossible to show that Master Y’s injury was caused by medical error.

ACC then received responses from the hospital and obtained further independent advice from another obstetric advisor, and an independent clinical organisational advisor. The obstetric advisor commented on the difficulties of pre-test counselling, and suggested the possibility of an organisational error. However, ACC advised that even if there was evidence of organisational error, it could not be considered because “the claim occurred before the legislation [Injury Prevention Rehabilitation and Compensation Act 2001] incorporating organisational error came into effect”. ACC’s clinical organisational advisor commented that there was no organisational error and stated: “The hospital was presented with a difficult situation and in the climate of uncertainty, responded, as an organisation, in an appropriate way.”

ACC noted advice from a professional advisor of the New Zealand College of Midwives, that the guidelines were not circulated to midwives. On 27 July 2004 ACC acknowledged that the risk of infection to Master Y would have been significantly reduced if his mother had been diagnosed as HIV-positive earlier in the pregnancy. However, ACC’s decision of 10 September 2003 to decline the claim remained unchanged.

ACC’s decision is currently being reviewed. On 20 January 2005 a review hearing took place. On 19 April the Clinical Advisor, Medical Misadventure Unit, informed HDC that ACC had obtained independent midwifery advice, which is currently being considered by the ACC Reviewer.

Response by the hospital

To assist in deciding what action to take on the complaint, information was requested from the hospital. On 20 January 2005 Dr H, Clinical Leader, provided a response to the complaint, on behalf of the hospital, about the care provided to Ms X.

Since 1999, the hospital has been proactive in promoting HIV screening in pregnancy. Shortly after Master Y's birth, the hospital was developing a policy/guideline. On 6 September 1999 a draft document, "HIV in pregnancy" was circulated to interested parties (people who might have wanted to contribute to the development of a policy) at the hospital aiming to ensure that pregnant women with, or at risk of, HIV receive coordinated care that meets their needs, and that the babies of these women are given timely and appropriate care. The draft made reference to the 1997 Ministry guidelines. However, the draft guideline never became an actual policy. Dr H explained that there were impracticalities in the counselling requirement. In his letter to the Medical Misadventure Unit dated 23 March 2004, Dr H discusses the difficulties the hospital had in formulating a policy with the proposed requirement for pre-test and post-test counselling to be offered by a staff member with special skills and knowledge in the area of HIV. He stated that "the process had been made too complicated and the process itself was creating significant barriers to testing".

There has been an active programme to educate doctors and midwives working at the hospital's District Health Board (DHB) about HIV screening. An obstetric physician, an infectious diseases paediatrician, and a paediatrician from the DHB have advocated for changes to the national guidelines. The DHB put a proposal to the regional ethics committee to introduce universal screening at the hospital. Pressure from the hospital clinicians played a part in the setting up of the recent National Health Committee review.

Dr H explained that Master Y is one of two children born at the hospital of the 21 New Zealand-born children who have developed HIV/AIDS from perinatal transmission in the last 13 years. The other child born at the hospital was born in 1995. His mother presented late in her pregnancy and it was not possible to treat her optimally. Since 1995, 22 mothers have been diagnosed as HIV-positive prior to delivery at the hospital; none of the children are HIV-positive. Master Y remains the only child with perinatally acquired HIV born at the hospital whose mother was not screened and diagnosed in pregnancy.

Ministry of Health

The Director-General of Health provided the following comments in relation to HIV screening in New Zealand:

"Incorporating clinical guidelines into practice is not a straightforward process and, with experience, we are learning more about effective ways to implement guidelines. There has been some education of health providers about HIV testing in pregnancy and the issue is now better understood. We do know that it takes time for practitioners to change their practice, and research has shown that assessment of pregnant women for risk factors for HIV infection has not been widely adopted in New Zealand. The finding prompted, in large part, the National Health Committee review of antenatal screening for HIV, which has, in itself, enhanced awareness of the issue."

The Director-General explained that the Ministry of Health is currently working on a response to the National Health Committee report (October 2004) in consultation with other stakeholders.

Code of Health and Disability Services Consumers' Rights

The following provisions of the Code of Health and Disability Services Consumers' Rights (the Code) are relevant to this case:

RIGHT 4

Right to Services of an Appropriate Standard

- 1) *Every consumer has the right to have services provided with reasonable care and skill.*
- 2) *Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.*

RIGHT 6

Right to be Fully Informed

- 1) *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, ...*
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Decision

Having reviewed all the available information, I have reached the following conclusions:

1. Ms X did not receive an appropriate standard of antenatal care from her community midwife and the hospital, in two respects:
 - a) she did not receive a comprehensive pregnancy risk assessment that included the risk of HIV infection; and
 - b) the possibility of infection was not adequately followed up subsequent to the review of her laboratory results by the haematologist.
2. Ms X did not receive the information that a reasonable woman in her circumstances would expect to receive about the risk of HIV infection and the availability of testing and treatment.

There were several factors present that placed Ms X at a high risk of having HIV infection. She came from Thailand, a high prevalence country, and had previously had

sexual contact in Thailand. She also had an unexplained anaemia reported by the haematologist, and cervical smear abnormalities requiring colposcopic surveillance.

3. The standard of care and level of information provided to Ms X may well have been similar to what she would have received from the majority of community midwives and public hospital women's health services in New Zealand in 1999 (with the possible exception of the inadequate follow-up of her laboratory results post-haematology review).

In particular, assessment of HIV risk and an offer of a test where risk factors are identified (in accordance with the Ministry of Health's 1997 guidelines on HIV in pregnancy) had not become accepted practice in 1999 – and in light of the very patchy implementation of the guidelines nationwide, could not be described as a “professional” or “relevant” standard that thereby became legally binding under Right 4(2) of the Code.

4. However, the fact that common practice was to undertake an incomplete assessment of a pregnant woman's risk of HIV infection does not mean that it was an appropriate standard of care under Right 4 of the Code. There is force to the point made in the complainant's submission dated 29 November 2004 to ACC:

“Sloppy practice throughout New Zealand in this area is not to be condoned because everyone is sloppy.”

It is ultimately for the Commissioner to determine whether care was of an appropriate standard (ie, the *Bolam* test of compliance with a “responsible body” of practitioner opinion is not determinative under Right 4). Given the state of knowledge about HIV infection and the availability of treatment to prevent perinatal transmission, in my view, women receiving antenatal care in New Zealand in 1999 were entitled to a comprehensive pregnancy risk assessment that included assessment of the risk of HIV infection.

5. I do not consider that the defence of “reasonable actions in the circumstances” (clause 3 of the Code) excuses the failures of the community midwife and the hospital. It is not an excuse (or a relevant circumstance) that other providers would have provided a similar standard of care and information.
6. It is clear from the above discussion that there are apparent breaches of the Code – in particular Right 4 (the right to services of an appropriate standard) and Right 6(1) (the right to information).

Section 38(1) of the Health and Disability Commissioner Act 1994 allows the Commissioner to take no action on a complaint if the Commissioner considers that, having regard to all the circumstances of the case, it is unnecessary or inappropriate to take any action. In deciding whether to take no action, the Commissioner may take into account the length of time that has elapsed between the date when the subject matter of the complaint arose and the date when the complaint was made (section 38(2)(a)).

In my opinion, it would be unjust (and inappropriate) to single out Ms A and the hospital for formal investigation in light of:

- a) the evidence of similar conduct by other antenatal providers in 1999;
- b) the passage of time (nearly six years) since these events;
- c) the acknowledgement by the hospital that Ms X received inadequate care and that the risk of HIV transmission to her baby could have been markedly reduced;
- d) the steps taken by the hospital since 1999 to improve HIV screening in pregnancy.

It is also of concern that other healthcare providers involved in Ms X's care were not alerted to the possibility of HIV infection, given the factors (discussed above) that placed Ms X at high risk of having HIV infection and postpartum fever.

As noted earlier, I consider that Ms X did not receive adequate care in terms of follow-up of her abnormal blood test results. It is of concern that Ms A and the unidentified doctor involved did not make an adequate record of their discussion or of the proposed follow-up care and management of Ms X. However, it would be impracticable at this late stage to determine the circumstances surrounding the follow-up subsequent to the abnormal blood test results. Ms A does not remember the details of the discussion, and the hospital is unable to identify the doctor involved. I have followed up this issue with Ms A and the hospital.

However, in relation to the other failures identified in my assessment of this complaint, I have decided to take no further action, but to take the steps set out below.

Follow-up steps

The failure to follow up abnormal test results and to offer an HIV test during Ms X's pregnancy had very serious consequences. This case highlights the urgent need for education of antenatal providers and for clear guidance from the Ministry of Health. I have brought this case to the attention of the Minister of Health and the Director-General of Health with a recommendation that national policy on "HIV Screening in Pregnancy" be determined and appropriate guidelines implemented in a more consistent and effective manner (with education of antenatal providers) as a matter of urgency. I have also provided copies of this anonymised report to the New Zealand College of Midwives, the Royal Australian and New Zealand College of Obstetrics and Gynaecology, the Royal New Zealand College of General Practitioners, the Royal Australasian College of Physicians, the New Zealand AIDS Foundation, the AIDS Epidemiology Group of the University of Otago, Family Planning Association, Women's Health Action, and the Federation of Women's Health Councils Aotearoa, for educational purposes.

I also intend to place a copy of this anonymised decision on the HDC website, www.hdc.org.nz, on Monday 13 June 2005, to draw media and public attention to the important issues raised by this case.