Executive summary

A randomised controlled trial of different approaches to universal antenatal HIV testing: uptake and acceptability

and

Annex: Antenatal HIV testing – assessment of a routine voluntary approach

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Executive summary (Main report)

Background and aim of study
With increasing optimism about the benefits of antenatal HIV testing, particularly in terms of measures that greatly reduce the risk of infection to the baby, there is a demand for effective, acceptable testing programmes and appropriate patient information. This randomised controlled trial (RCT) was designed to compare different ways of offering testing to all pregnant women, with the aim of acquiring information about what predicts uptake and how women respond to the offer of testing, in order to define the optimal approach.

Methods
The setting was a hospital antenatal clinic covering the majority of the population of Edinburgh City. The target group was all pregnant women booking at the clinic over 10 months. The design was an RCT involving four combinations of written and verbal communication, followed by the direct offer of an HIV test with written consent required for testing. Women were sent either a specific leaflet about HIV testing in pregnancy or a leaflet containing information about HIV testing amongst information on the other antenatal blood tests. At the clinic, a core group of ten trained midwives offered the test, following either minimal or comprehensive pre-test discussion protocols printed on cards. The control group received no information and no direct offer of a test, although testing was available on request (the pre-trial situation). Participants were 3024 pregnant women, of whom 2704 (89%) completed a questionnaire which determined acceptability of testing, at their booking appointment. A sub-sample of the participants (n = 788) also completed a questionnaire at their 32-week appointment. The main outcome measures were uptake of HIV testing, knowledge of HIV and other antenatal tests, satisfaction with the consultation, anxiety, attitudes towards pregnancy and perceived benefits of testing. Opinions about testing during pregnancy were also sought using both quantitative and qualitative measures. Midwives’ knowledge and attitudes were assessed to investigate their effect on women’s uptake of testing.

Results

Uptake
Although uptake was not high, offering the HIV test resulted in a significantly higher uptake (35%) than if they had received the ‘HIV-specific’ leaflet than if they had received the ‘all blood tests’ leaflet. Being unmarried and younger were multi-variate predictors of uptake; being socially deprived was a univariate predictor, as was being unemployed. Parity and area risk (as defined by the prevalence of HIV infection in different postcode areas of Edinburgh) were not related to uptake. Age was the only demographic variable that modified the effect of the different ways of offering testing: older women (aged ≥ 39 years) were more likely to take the test if they had received the ‘all blood tests’ leaflet than if they had received the ‘HIV-specific’ leaflet.

Demographic predictors of uptake
Being unmarried and younger were multi-variate predictors of uptake; being socially deprived was a univariate predictor, as was being unemployed. Parity and area risk (as defined by the prevalence of HIV infection in different postcode areas of Edinburgh) were not related to uptake. Age was the only demographic variable that modified the effect of the different ways of offering testing: older women (aged ≥ 30 years) were more likely to take the test if they had received the ‘all blood tests’ leaflet than if they had received the ‘HIV-specific’ leaflet.

The midwife effect
The midwife had an important effect on uptake. Clients’ uptake rates ranged from 11% to 48% among the ten midwives, and the midwife seen was the second most significant predictor of uptake after being offered the test. The most striking influence on uptake rates seemed to be the midwives’ attitudes. In particular, the midwife with the highest uptake had the most positive attitude towards testing, having no doubts that the test was beneficial for all pregnant women, that testing should be offered in the clinic and that it was her role to increase uptake.

Acceptability of testing
The majority (88%) of pregnant women who responded to the questionnaire were in favour of antenatal HIV testing. The most frequently cited reason for taking the test was that it was a good idea to have as a routine test, although many women were also concerned about the risks to the baby. Perceived low risk due to a stable relationship or not being in a ‘high-risk group’ seemed to be the main reason for not taking the test.

Anxiety (at booking or follow-up), satisfaction with the consultation, general knowledge about HIV, knowledge about other antenatal tests and attitudes towards pregnancy were all unaffected either by offering the test per se (compared with the control group) or by method of offering the test. However, specific knowledge about HIV transmission from mother to baby was affected by method of offering the test: women who received the ‘HIV-specific’ leaflet and the comprehensive discussion were most likely to have this knowledge.

Time taken for discussion
The average time taken for the comprehensive protocol was 7 minutes 40 seconds (SD = 4 minutes 30 seconds); for the minimal protocol it was 4 minutes 30 seconds (SD = 3 minutes 5 seconds).

Conclusions
Contrary to the view of many healthcare providers, women had a positive attitude towards being offered HIV testing in pregnancy and the offer did not create undue anxiety or dissatisfaction, nor was it inappropriately time-consuming. Moreover, the type and extent of information given to pregnant women about HIV testing affected their knowledge but not whether they took the test.

These findings indicate that the length or style of presentation to pregnant women is immaterial, although it is important that the benefits of testing for the baby are stressed. Instead, the focus of research and policy-making should be on the midwives, as their attitudes are likely to be more important in determining uptake.

Uptake rates were much lower than those reported in other European countries, and among those offered an HIV test only one of the two previously unknown HIV-positive women agreed to be tested. So, although women find the test offer acceptable, it seems that this approach to offering the test, in which women are given information and then asked whether or not they want the test, is not an effective way of achieving high uptake and detection rates.

Implications for further research and suggestions for the offer of testing

• In areas where unlinked anonymous HIV testing indicates appreciable levels of undetected HIV infection in childbearing
women a direct offer of testing to all women should be considered.

- Both ‘HIV-specific’ and ‘all blood tests’ leaflets have advantages. As a compromise we recommend assessment of a leaflet containing information about ‘all blood tests’, but including some more information about HIV, specifying clearly the benefits of testing during pregnancy.

- A minimal approach to discussion will cost less in terms of midwives’ time, but should probably contain specific information on the benefits of testing as our data suggest that this will increase women’s knowledge.

- The data suggest that midwives are the key to increasing uptake and thus good training is fundamental when an increase in uptake is desired. Midwives should be given information about HIV and HIV testing, but it is likely that increasing their positive attitudes towards testing and their ability to convey information about the benefits of testing will have a greater effect on uptake. More detailed research should attempt to identify the midwives’ individual characteristics that affect uptake rates.

- In the light of the evidence that women find the test offer acceptable and yet uptake remains fairly low, we propose that in areas where an increase in uptake of testing is desired, a routine approach to testing (i.e. the test is done automatically unless the woman chooses not to be tested) should be considered. This method would have to be assessed carefully in terms of uptake and women’s response. [An assessment of a routine voluntary approach was subsequently carried out. The results are presented in an annex to the main report (see pages 81 to 106). A summary of the annex report follows.]

**Executive summary (Annex)**

**Objectives**

The aim of the study was to assess a routine voluntary model of offering antenatal HIV testing in pregnancy, and to compare this with the ‘opt-in’ model previously studied in the randomised controlled trial (RCT) (see above). The routine voluntary model is based on similar requirements for information, choice and consent, but with a change in emphasis so that the test is done routinely unless the woman declines.

**Methods**

This was an observational study carried out in the antenatal clinic of a large obstetric unit serving the majority of the population of Edinburgh City. (The same clinic was the setting for the RCT.) The target population was all women attending for their first appointment in the hospital antenatal clinic between 2 February 1998 and 1 May 1998.

Before their booking visit, women were sent an explanatory letter, and a leaflet describing all blood tests which might be carried out. These included the HIV test, and the leaflet explained the advantages in terms of prevention of transmission of HIV to the baby. The midwife discussed HIV testing with the woman at the clinic and the offer of testing was made. After the clinic, the women were asked to complete a questionnaire.

The main outcome measures were the women’s uptake rate, satisfaction, anxiety, and knowledge, and the time taken to discuss HIV.

**Results**

Over the study period, 924 women booked at the clinic and of these 816 (88%) had an HIV test. The only demographic and situational features affecting uptake were parity and social deprivation: women having their first baby, and women living in areas of deprivation, were more likely to take the HIV test. The midwife had an effect of borderline statistical significance ($p = 0.05$). The questionnaire response rate was 99% (916/924). Most women (793/904, 88%) responded positively to the question, ‘do you think the HIV test should be a routine test like all the other blood tests during pregnancy (i.e. it’s done unless you say you don’t want it)?’. Compared with the control (n = 994) and ‘opt-in’ (n = 2030) groups in the RCT, the routine voluntary model resulted in significantly greater specific knowledge about zidovudine ($p < 0.0001$) and resulted in lower levels of anxiety ($p < 0.0001$). The level of satisfaction was not affected by how women were offered the test. The mean time taken in discussion was 2 minutes 34 seconds.

**Conclusions**

The routine voluntary model is well accepted by midwives and pregnant women. The approach was not time-consuming and required no extra staff. It is likely to be more effective in case finding because of the high uptake rate. Comparisons with groups in the RCT are confounded by the 1-year interval between the two studies: women’s and midwives’ attitudes to HIV testing might have changed. Nevertheless, the fact that the routine voluntary programme was associated with lower levels of anxiety, higher levels of knowledge and the same degree of satisfaction is reassuring. There is no evidence that women found it difficult to decline a test.

We cannot conclude that this approach will achieve a similar outcome in London, where there are more complex issues of language and cultural heterogeneity. But, provided that there are safeguards to ensure that women can make a fully informed choice, a routine voluntary approach as we describe is in keeping with recent guidelines and may be acceptable and appropriate in other clinics in high prevalence areas.

**Recommendations for future research**

- Routine voluntary HIV testing should be evaluated in antenatal settings in London.
- The appropriateness of introducing routine voluntary testing into non-antenatal settings (e.g. genitourinary clinics) should be investigated.

**Publication**

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care. It was identified as a priority by the Population Screening Panel and funded as project number 93/24/11.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

Reviews in Health Technology Assessment are termed ‘systematic’ when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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The editors have tried to ensure the accuracy of this report but cannot accept responsibility for any errors or omissions. They would like to thank the referees for their constructive comments on the draft document.