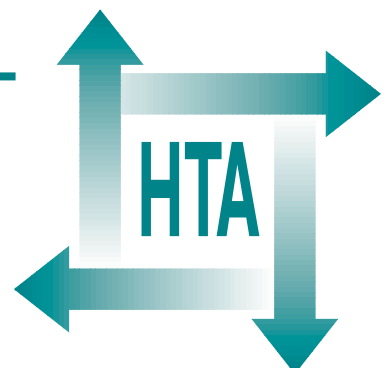


A randomised controlled trial of different approaches to universal antenatal HIV testing: uptake and acceptability
and
Annex: Antenatal HIV testing – assessment of a routine voluntary approach

WM Simpson
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**A randomised controlled trial of
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**Annex: Antenatal HIV testing –
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Simpson WM, Johnstone FD, Hart GJ, Boyd FM, Goldberg DJ. To test or not to test? What makes pregnant women decide to take an HIV test? *Psychol Health Med* 1998; **3**:327–35.

Simpson WM, Johnstone FD, Goldberg DJ, Gormley SM, Hart GJ. Antenatal HIV testing: assessment of a routine voluntary approach. *Br Med J* 1999; in press.

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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.

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List of abbreviations

AIMS	Association for Improvement in Maternity Services
AZT	zidovudine
AFP	α -foetoprotein
CF	cystic fibrosis
df	degrees of freedom
GP	general practitioner
KW	Kruskal–Wallis *
MH	Mantel–Haenszel *
NCT	National Childbirth Trust
NS	not significant *
RCT	randomised controlled trial
STAI	State Trait Anxiety Inventory

* Used only in tables

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 making the test available on request (control group; 6%). The four methods of offering the test did not result in different uptake rates (i.e. uptake was unaffected by type of leaflet or style of pre-test discussion). Of the 760 women tested during the trial, one woman was newly identified as HIV positive. Data on unlinked anonymous HIV testing of dried blood spots impregnated on neonatal metabolic screening cards were studied and showed that three HIV-infected women were not detected during the 10-month trial: one was in an intervention group; the other two were in the control group.

Demographic predictors of uptake

Being unmarried and younger were multivariate 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 15% 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.

Chapter I

Introduction

Background

There is increasing optimism about the benefits of antenatal HIV testing. Specifically, there are now known benefits of early diagnosis of HIV infection for the woman and her child. Zidovudine (AZT) therapy for the mother antenatally and in the intrapartum period and for the baby postnatally can reduce vertical transmission by 67%.^{1,2} Not breastfeeding can reduce vertical transmission by 14%.³ Mode of delivery is also thought to have some effect in reducing the risk of transmission and it is currently the subject of a randomised controlled trial (RCT).⁴

This positive attitude towards antenatal HIV testing had led to a demand for effective, acceptable programmes of testing and appropriate patient information.⁵ The present study was designed to respond to this demand by comparing different ways of offering testing to all pregnant women in a RCT. For a programme to be effective, it is important that women who are HIV positive are identified and therefore we need to know how to increase uptake. To define an acceptable programme, we need to have a better understanding of how pregnant women respond to the offer of an HIV test. Also, the level, style and content of patient information needs to be evaluated.

Edinburgh City had a peak prevalence of HIV infection of 1:250 deliveries in 1986. The prevalence has since fallen but remains significant in comparison with many centres (1 in 660 deliveries from 1990 to 1995).⁶ However, before this trial there was no universal testing policy in Edinburgh and only a small percentage (less than 1%) of women were selectively offered the test antenatally, usually because they had a history of intravenous drug use. Because of this relatively high prevalence, but lack of previous universal testing policy, Edinburgh was ideally suited to run this RCT.

In London, where the rate of infection in pregnant women is high (i.e. 1 in 580⁷), a recent study investigated each of London's 33 maternity units.^{7,8} Testing policies were found to result in very low uptake rates (< 10% on average) and a very low detection rate of HIV-positive pregnant women (22 out of 322). The authors, investigating the

practice of testing in these units, found that few had written protocols; leaflets, when available, varied considerably; midwifery staff received little or no training and practice was inconsistent. This situation requires urgent action to define a standard protocol that is both effective and acceptable to the women.

Currently, antenatal testing policies, practices and uptake rates vary both within the UK^{8,9} and in other countries^{10,11} and this has encouraged debate about how testing should be offered: to all women (universal policy), selectively (for those with recognised risk factors) or on a 'request only' basis.

Another conflict of opinion has been whether the test should be offered with comprehensive information, as would be done in an HIV-testing clinic, or whether it should be offered more in line with the other antenatal blood tests, with minimal information. Minimal information may be more likely to achieve high uptake^{10,12} but may not provide adequate information to allow informed choice. Comprehensive information, on the other hand, aims to ensure informed choice but may result in high costs in terms of midwife time and increased anxiety.¹³ The relative merits of 'opt-in' and 'opt-out' approaches have also been discussed: an 'opt-in' approach is one in which the woman is asked if she wants to take the test and often involves written consent, whereas an 'opt-out' approach requires the woman actively to reject testing because it is done in a routine manner. Although various studies have examined the outcomes of the different policies^{5,8,13} there has not been a systematic comparison of the different methods. Women's attitudes to HIV testing have previously been addressed,^{14,15} but not as a direct effect of different ways of being offered testing.

Since the majority of women are at low risk of being infected, what are the benefits and disadvantages for those testing negative? The benefits of testing may be that it provides reassurance. Indeed, a study by Larsson and colleagues¹⁵ found that half of a sample of Swedish women taking the HIV test experienced feelings of security. However, anxiety may have been engendered by testing in the first place. In the Swedish study,¹⁵ 16% of the

women felt that the test itself aroused anxiety. There is evidence that women find the offer of another antenatal test (cystic fibrosis (CF) carrier testing) anxiety provoking¹⁶ and HIV screening has been found to be one of the more worrying antenatal tests.¹⁴ There is also the possibility that discussion about HIV testing, especially if it causes anxiety, may interfere with the comprehension and retention of other important information given at the booking clinic. Possible feelings of resentment about being offered the test or having to discuss the test's implications may reduce satisfaction with the midwife or the hospital in general. Moreover, if discussion about HIV awakens concerns about the fidelity of a current or previous partner, it could have some effect on attachment to the early pregnancy.

Although the Department of Health guidelines¹⁷ state that pre-test counselling should cover five main components for pre-test discussion, it has been argued that it may be unreasonable to conduct mandatory detailed counselling, particularly since there is so much information already provided at the antenatal booking visit.¹⁸ It is important to find out what level of pre-test discussion is acceptable to women in terms of allowing informed choice without causing anxiety or dissatisfaction. We also wanted to determine whether women would respond better (in terms of knowledge and anxiety) to written information about HIV which appeared routine (i.e. just another blood test) or to a special leaflet with detailed information about the HIV test and its implications in pregnancy.

The present study aimed to determine whether different methods of a universal offer of testing, in terms of different levels of information-giving, would lead to significantly different uptake rates. We were not able to assess the differences between an 'opt-in' and 'opt-out' approach because an 'opt-out' approach has not been considered acceptable practice in the UK, due to concerns about the negative impact that testing might have (but see annex, page 81). The second, and equally important, aim of this study was to assess the impact of the different methods on the women's response in terms of her satisfaction, anxiety and knowledge. Also, the roles of both demographic and situational factors were examined to determine their independent effect on uptake and their interaction with the method of offering the test. The goal was to

have sufficient information to define the most effective and acceptable approach to testing.

Research questions

The main research question was as follows.

1. What is the effect of different ways of offering HIV testing, compared with controls on:
 - (a) uptake rates
 - (b) psychological impact
 - anxiety (immediately after booking and at follow-up)
 - knowledge about HIV infection and transmission
 - knowledge about other antenatal tests
 - satisfaction with the consultation
 - attitudes towards pregnancy (immediately after booking and at follow-up)
 - perceived benefits of testing?

Further research questions were as follows.

2. How many HIV-positive women are detected/undetected by the programme?
3. Does the midwife have an effect on uptake and impact?
4. Do age, parity and socio-economic variables have an effect on uptake? Do these variables modify the effect of the different ways of offering testing?
5. Is perceived risk of HIV related to uptake?
6. Are pregnant women in favour of HIV testing in pregnancy?
7. How do pregnant women think HIV testing should be offered to them?
8. What reasons do women give for taking or not taking the test?
9. Is the HIV test any more or less anxiety provoking than any of the other antenatal tests?
10. Is the HIV test valued as much as other antenatal tests?
11. Are participants who took the HIV test satisfied with the way the result was given?
12. What are the costs for each of the methods of offering testing?
13. How much knowledge do the midwives have and what are their attitudes towards testing? Are there relationships between the midwives' knowledge and attitudes and uptake rates?
14. What do pregnant women really think about being offered HIV testing, in their own terms?

Chapter 2

Methods

The study was approved by Lothian Reproductive Medicine Ethics Committee.

Setting

The study took place in the Simpson Memorial Maternity Pavilion which is situated in the centre of the City of Edinburgh. It is one of the largest maternity hospitals in Scotland, with over 5000 deliveries per year.

Target sample

The target sample was all pregnant women attending the antenatal clinic for their first (i.e. booking) visit to the hospital during the 10-month period from early May 1996 until the end of February 1997. The only exclusion criteria were HIV-positive status and language difficulty when no interpreter was available. The target sample size of 3000 was chosen to have approximately 90% power to demonstrate a significant change ($p < 0.05$) in uptake from 70% to 80% between intervention groups.

Design

The study was a RCT. The randomly allocated interventions (*Table 1*) were different presentations of an offer of voluntary named HIV testing. The different presentations involved two different types of leaflet and two different levels of discussion (see chapter 3 for details).

The four intervention groups were directly offered the test by a midwife (universal policy). The control group were not routinely offered a test, which was the pre-study clinical situation.¹⁹ Before the study, women were selectively offered the test if seen to be at risk on the basis of information in their notes about intravenous drug misuse (selective policy). This remains the situation in other parts of Scotland, except Dundee. However, in the light of the recent Department of Health²⁰ push for universal testing, and our belief that good practice should include easy availability of testing, we sought to make the control group more aware of this. Thus, the control group were informed by letter (see appendix 1) about the study in the same way as the other groups and were told that the test was available for everyone, even those who were not actually offered a test by the midwife. If they wanted the test, it was made clear that they should just ask. Posters were displayed in the clinic to re-emphasise this message (see appendix 2).

The main study outcomes, as outlined in the list of research questions (see chapter 1), were measured by a midwife checklist and a patient self-completed questionnaire immediately following booking. Further outcomes were measured using a patient self-completed questionnaire at the 32-week follow-up visit.

Procedure

All women for whom a booking appointment was made during the 10 months of the study

TABLE 1 Interventions and projected number of participants

Group	Leaflet	Discussion protocol	Offered testing?	Projected no. of participants
1	None	None	No*	1000
2	'All blood tests'	Minimal	Yes	500
3	'All blood tests'	Comprehensive	Yes	500
4	'HIV-specific'	Minimal	Yes	500
5	'HIV-specific'	Comprehensive	Yes	500

* HIV testing was available on request for this group and was advertised in a letter about the study sent to all women and by poster in the clinic

were randomised. In response to referral from her general practitioner (GP), an antenatal number for each patient was generated by the hospital computer. This marked the point of formal trial entry and each woman was allocated a group code on the basis of random assignment by a computer program: within each successive block of 24 women, eight were allocated to the control group and four to each of the intervention groups. Assignment was therefore free from any possible bias.

A patient information letter (see appendix 1) was then sent to all women, with the booking information package, explaining the nature and purpose of the study. It explained that the woman could choose whether or not she wanted an HIV test and that the questionnaire was voluntary. The relevant leaflet, if applicable, was enclosed within the posted information.

Before each clinic, the research midwife put a coded sticker inside the patient's notes to indicate to the clinic midwives which of the five intervention groups the patient was in. The clinic midwife then knew which leaflet the woman had received and which level of counselling she should provide.

When the woman arrived at the clinic, she was approached by the research midwife to ensure that she was happy to participate in the study. It was reinforced that it was her choice whether or not to accept testing and whether or not she wished to complete the questionnaire. If the woman did not want to be involved in the study in any way, the midwife was notified and the test was not offered. Exclusion criteria information (e.g. if someone had a language difficulty and there was no interpreter available) was only available after randomisation and after the study information had been sent, so exclusions were made at time of booking. In such cases, the midwife was notified and the test was not offered.

The majority of the bookings were carried out by ten midwives who were all trained to offer the test (see page 5 for further details). When the woman was seen by a midwife, the HIV test was discussed and offered alongside the other antenatal screening tests if the woman was in one of the four intervention groups. The two discussion protocols were printed on card and available in each consulting room for easy reference. If the woman was in the control group, the midwife did not mention HIV testing unless the woman asked about it. If this occurred, it was at the midwife's discretion what level of information and discussion to provide.

If the woman decided to take the test, she was informed of the procedure for receiving both positive and negative results. She was required to sign a consent form which also asked for the address to which the result was to be sent. In this event, the blood sample that was used to test for syphilis was also tested for HIV. Samples to be tested for HIV were marked clearly before being sent to the laboratory.

For each woman seen, the midwives completed a checklist. They noted how long it took to discuss HIV testing (if applicable), whether the woman took the test, whether the partner was present at the consultation, whether the woman had had a previous test, whether she or her partner was an intravenous drug user and the nationality of the patient if English was not her first language.

After her booking appointment, each woman was asked by the research midwife if she would complete the Booking questionnaire. She was asked to complete it before she went home, but if she could not wait, she was provided with a stamped addressed envelope to return the completed questionnaire.

The research midwife kept a confidential record of all women taking the HIV test. She received the results from the laboratory and sent negative results through the post within a week of testing. In the event of a positive result, the woman was contacted by phone by the midwife who had seen her at booking and asked to return to the clinic for further, same-day testing.

Linkage with data from unlinked anonymous HIV testing survey of neonates

To determine HIV prevalence among childbearing women in Scotland, unlinked anonymous HIV testing of dried blood spots from Guthrie cards obtained from neonates has been performed since January 1990. Guthrie cards corresponding to all pregnant women included in the study were coded to establish if the women had belonged to either the control or the intervention group. This enabled the investigators to determine how many women in the study population who did not have an HIV test were antibody positive.

Midwives training and monitoring

The study involved a small number of midwives ($n = 10$) who worked only in the antenatal clinic.

Each of these midwives did more than 130 bookings (range, 134–492) over the 10-month period. Another ten midwives were also involved in offering the test, but they were not analysed individually in the final sample of midwives because they each did very few bookings (range, 2–62 bookings): some were temporary staff and some worked in other parts of the hospital but occasionally did bookings in the clinic. Instead these ten midwives were grouped together as one for the analyses. However, all 20 midwives were given training. During the course of the study any staff rotation was minimised. This allowed for close monitoring by the research team and relatively easy administration of training sessions.

Initial training before the study started involved 2 half-days. The first session on the first half-day was led by a research nurse who provided information on the basic virology of HIV, heterosexual and vertical transmission and the interventions to reduce vertical transmission. In the second session, an experienced HIV counsellor outlined the important issues for HIV counselling and

used role play to highlight some of the issues that could arise.

The second half-day was run by the project leader with the purpose of outlining the aims of the study, the research questions and the midwives' role. The discussion protocols were introduced and discussed at length, emphasising the importance of the distinction between the two and accepting feedback from the midwives regarding content and style. All of the midwives were provided with a training package including notes from the two sessions and relevant journal articles. They were also given the discussion protocols to study at home. After the first few weeks of the study, we organised occasional meetings to deal with any unexpected issues, to identify further problems with the discussion protocols and to provide support. The researcher carried out periodic monitoring (including feedback) of all midwives' consultations to ensure consistency and that the two different types of discussion were kept distinct: each midwife was observed at least twice for each of the two protocols and was given feedback on her delivery of information.

Chapter 3

Leaflet development

This chapter describes the development of the two leaflets used in this trial: the ‘HIV-specific’ leaflet (appendix 3) and the ‘all blood tests’ leaflet (appendix 4).

A previous survey²¹ of three leaflets designed to give pregnant women information about HIV testing in pregnancy found that they contained factual errors and omissions. They varied in readability and some bias either towards or against testing was detected in all three leaflets. Analyses of presentation found that one of the leaflets was presented in an amateur, ‘boring’ manner.

Sherr and Hedge²¹ concluded that leaflets should aim to be as objective (unbiased) as possible. They should always be checked for readability and routinely piloted before use and they should be clearly and attractively presented. Moreover, Sherr and Hedge²¹ argued that leaflets should not be seen as an alternative to pre-test HIV counselling, but only as one small component of the process towards making a decision about testing.

In the development of the leaflets for this trial, previous research findings²¹ were taken into consideration in an attempt to produce a more effective information package for use with this particular population. Also, in the light of the argument that leaflets should not replace counselling, the present leaflets were designed as a useful starting point for further discussion and decision-making with trained midwives.

Development of the ‘HIV-specific’ leaflet

Review of existing leaflets

Some leaflets about HIV testing in pregnancy have already been written. A review was carried out of four of these existing leaflets. Leaflets 1 and 2 were professionally designed by AIDS registered charities. Leaflet 3 was developed for offering routine screening for HIV testing in pregnancy in another Scottish hospital, and leaflet 4 was designed for the same purpose in a London hospital. Readability analyses was carried out on these four leaflets using the Flesch formula²² on Microsoft Word v.7. Results are shown in *Table 2*. None of these previous leaflets was entirely suitable for our purpose. Leaflet 1 had a poor readability score and its approach was too wide for our purpose in that it suggested testing before becoming pregnant. Leaflet 2 was very comprehensive and readable, but was too long for our purpose – we needed something that would be read along with many other leaflets sent to pregnant women before booking. Leaflet 3 was biased towards testing and presented the test’s main purpose as a useful way of understanding about the spread of HIV. It also lacked detailed information about the benefits of testing which we thought was a necessary inclusion considering that previous research has shown that one of the main predictors of uptake of HIV testing is perceived benefits of testing to the woman herself.²³ Leaflet 4 was highly readable and a good length, but was not particularly eye-catching in its design.

Although none of these leaflets was exactly suitable for our purpose, together they provided

TABLE 2 Readability analyses of pre-existing leaflets on HIV testing in pregnancy

Analysis item	Leaflet 1	Leaflet 2	Leaflet 3	Leaflet 4
Number of words	1341	2272	539	784
Number of sentences	74	154	41	55
Readability score	59.4	65.2	69.4	71.3
Proportion of population who would understand ^{24*}	77%	90%	90%	90%

* These percentages are for the population aged between 25 and 65 years

an invaluable resource for defining the many important issues about HIV testing for pregnant women. We interpreted the main issues as being:

- basic information about HIV infection and transmission
- an explanation of why the test is offered in pregnancy
- what the test involves and what the results mean
- benefits of testing with particular reference to AZT and avoidance of breastfeeding
- disadvantages of testing
- the current situation regarding life insurance
- details of testing at the clinic.

Writing the leaflet

Having defined the relevant issues to include in the leaflet (see above), a first draft was written. An attempt was made to ensure that the leaflet was clear, readable and attractively presented. It was also written with the aim of being objective – that is neither particularly for nor against HIV testing.

Expert feedback

Feedback about the leaflet was sought from a variety of experts (see page 10) in order to check for factual errors and omissions. In particular, extensive feedback and help with style and presentation were received from a Senior Health Promotion Officer with experience in creating HIV/AIDS health promotion materials. Changes in the wording, ordering of the lay-out and style were made in response to these comments.

Piloting

The leaflet was then ready for piloting with the target group (i.e. pregnant women) to ensure its acceptability.

Participants and method

The pilot group comprised 23 pregnant women attending the antenatal clinic for their first visit. This sample was drawn from the population to be included in the trial for which the leaflet was being designed. Each women was given the leaflet in the waiting room when they attended for their appointment. They were told that the leaflet was being designed for use in a large study of HIV testing in pregnancy. They were asked if they would mind taking the time to read through the leaflet and then discuss what they thought about it with the researcher. After reading the leaflet the women were interviewed by the researcher using a set of open-ended questions.

The response rate was 100%. No one who was approached refused to read the leaflet and comment on it.

Interview questions

The questions concerned: the leaflet's readability and its lay-out; whether the information given was adequate or too much, with reference to specific topics; whether there was enough information to make a choice about testing; whether the leaflet seemed to be for or against testing, or neutral.

Results

Although the questions were open-ended, the participants' responses could be fitted easily into categories. *Table 3* gives patients' assessment of the leaflet.

Alterations to leaflet

A number of alterations were made following piloting. Although the findings from piloting were generally encouraging, some detailed comments from the women helped us to make improvements. It was suggested that the most

TABLE 3 Pilot assessment of the 'HIV-specific' information leaflet among pregnant women

Pilot assessment item	No. (%) of women*
Assessment of readability	
Very easy/easy	18 (78)
Quite easy	4 (17)
Difficult	0
Unsure	1 (4)
Anything confusing or unclear?	
No	18 (78)
Yes	5 (22)
More or less information needed?	
More	5 (22)
Less	4 (17)
About right	14 (61)
Could the lay-out be improved?†	
No	18 (78)
Yes	3 (13)
Is there enough information to make a decision about testing?†	
No	6 (26)
Yes	13 (56)
Don't know	2 (9)
Bias for or against testing?†	
For	10 (44)
Against	0
Neutral	10 (44)
* Responses to interview questions (see above)	
† Missing data because the women were called into their consultation	

important section was the one explaining why the HIV test is offered to pregnant women. This section was therefore placed on the first page of the leaflet. One woman thought that more detail was needed about how the test was actually done, so we added some details about taking the blood sample in the section 'What will happen at the clinic?'. Some women thought that the sections on 'What is HIV?' and 'How is HIV spread?' were relevant and important, but others thought they were unnecessary. These sections were therefore moved to the back flap of the leaflet so that they could be used as a reference if required.

The finding that ten women thought that the leaflet was pro-testing pointed out that the leaflet was not written in as objective a way as we had planned. Therefore the section 'Why can taking the test be a bad idea' was moved to the inside of the leaflet from the back flap to make the negative aspects of testing more prominent. However, from comments made, it seemed that women thought that the mere presence of the leaflet implied that taking the test was a good idea.

Some general comments were also useful. Detail on how to access more information was requested, so details of the two main clinics offering HIV testing in the area were given on the back page of the leaflet.

Overall evaluations

Spontaneous overall evaluations of the leaflet were generally positive. Only two women made the comment that the leaflet might worry people. Positive comments included 'I learned something new', 'It's very positive' and 'It's good to see something on HIV testing in pregnancy'.

Final version

Computer calculations showed that the final leaflet had 1241 words and 89 sentences and a Flesch score of 63.4. Compared with the four existing leaflets reviewed above (*Table 2*), the Flesch score was regarded as not high enough. An attempt was thus made to increase reading ease. The best Flesch score that could be derived without altering the overall style and content of the leaflet was 65.0. This indicates that 90% of the population aged between 25 and 65 years would be expected to be able to read the leaflet.²⁴ The final version of the leaflet is reproduced in appendix 3. To provide a professional finish, the leaflet was printed on pre-printed two-coloured card.

Development of the 'all blood tests' leaflet

The aim of the development of this leaflet was to produce written information that would make HIV seem a normal part of all the blood tests that were available at the clinic. However, it still had to be clear that testing for HIV would not be done without written consent.

This leaflet was written by a midwife (FB) and an obstetrician (FJ). It contains two sections: one entitled 'Tests available, but not routine' which incorporates hepatitis B and HIV testing, and the other entitled 'Blood tests which are routine for all women at booking' which deals with the full blood count, blood group, syphilis and rubella tests.

It was written and presented in a similar style to the 'HIV-specific' leaflet and produced on the same card. The HIV section was a short summary of the 'HIV-specific' leaflet giving brief details about the virus, transmission from mother to baby, and the test and results. It stated that special care could be given to the mother if she were positive to make it less likely that the baby would become infected, but it did not provide specific details.

Feedback was sought from various experts (see page 10) and changes were made accordingly.

Piloting was carried out using the same questions as used for the 'HIV-specific' leaflet, with a different group of 22 pregnant women. Only one of the women questioned thought that the leaflet was not easy to read. More women ($n = 12$) thought that the leaflet gave the right amount of information than thought it gave too much ($n = 6$) or too little ($n = 2$), so the length was kept approximately the same. We made changes to the content and lay-out in response to comments received.

When asked whether there was enough information in the leaflet to make a decision about HIV testing, 12 women said that there was, six said there was not, and one said 'don't know'. Three women did not answer the question. Interestingly, one criticism of the leaflet was:

HIV is too matter of fact. It has major implications for the woman but it is written in the same way as information about the full blood count.

This was exactly the response to this leaflet that we wanted to achieve for comparison with the 'HIV-specific' leaflet in the trial.

Summary

A review of existing HIV leaflets led to the conclusion that a new 'HIV-specific' leaflet would have to be designed to meet our specific requirements and to be as effective as possible. This chapter has reported on the development and piloting of a specific leaflet to give pregnant women information about HIV testing and a general leaflet to give information about HIV testing alongside information on other blood tests in pregnancy.

Piloting of both leaflets among small groups of pregnant women indicated that most of the women found the leaflets easy to read. It was originally planned that the leaflets should be as 'neutral' about HIV testing as possible and changes were made in the 'HIV-specific' leaflet to make negative aspects of testing more prominent. However, since the planning of this leaflet, testing has become more generally supported due to increasing certainty of the evidence regarding transmission. Thus we do not believe it is now a problem that several women felt the mere presence of the leaflet implied testing was a good idea.

The final readability scores were 65 of the 'HIV-specific' leaflet and 66 for the 'all blood tests' leaflet, which indicate that 90% of the population would be expected to understand them.²⁴ Although further development was impossible in this study due to lack of time for more piloting, perhaps future development could improve these scores.

This may seem to be a long and time-consuming process, but leaflets form the basis of communication with a very large number of pregnant women and so every effort was justified in making sure that our leaflets were optimally readable and useful. We hope that the leaflets can still be improved and adapted for different communities. Assuming continuing reassuring information from follow-up of AZT-treated babies and improving HIV management in adults with combination therapy, some of the benefits of testing will be more secure and this should be reflected in the information given to women.

Although the leaflets were designed as an addendum to pre-test counselling, it was found that, surprisingly, more than half of the women

in both pilot groups felt that the information given would be enough for them to make a decision about taking the test. This finding conflicts with views held by participants in a qualitative group analysis of a similar leaflet in a previous study in London.²¹ This may indicate differences in views about the necessity of pre-test counselling in different areas (London and Edinburgh). The difference may also lie in the selection of the sample. The previous study involved women who had recently delivered their babies, whereas in our study the women were about to have their booking consultation and were therefore about to make decisions about several prenatal tests. The trial for which this leaflet has been designed aims to provide more insight into pregnant women's views about the extent of pre-test discussion that they want to receive.

List of sources of professional help and feedback

We would like to thank all the people who gave us expert feedback on earlier drafts of the leaflets:

- Lesley Reid, Senior Health Promotion Officer, Lothian Health.
- Debbie Vowles, Women's Health Promotion Officer, Terrence Higgins Trust, London.
- Ian Chrystie, Virologist, St Thomas's Hospital, London.
- Mary Simpson, Research Midwife, Simpson Memorial Maternity Pavilion, Edinburgh.
- Wang Liston, Consultant Obstetrician, Simpson Memorial Maternity Pavilion, Edinburgh.
- Beverley Cummins, HIV Specialist Counsellor, City Hospital, Edinburgh.
- Rhona Wyld, HIV Research Nurse, City Hospital, Edinburgh.
- Stephanie Gardiner, Midwifery Sister, Simpson Memorial Maternity Pavilion, Edinburgh.
- Liz Ferguson, Staff Midwife, Simpson Memorial Maternity Pavilion, Edinburgh.
- Val Morrison, Health Psychologist, Queen Margaret College, Edinburgh.
- Beth Alder, Health Psychologist, University of Dundee.
- Sheila Burns, Consultant Virologist, Royal Infirmary of Edinburgh.

Chapter 4

Development of discussion protocols

Two different discussion protocols were developed for comparison in the trial, minimal (appendix 5) and comprehensive (appendix 6), with the aim of determining the optimal extent of pre-test discussion required to allow informed decision-making without causing unnecessary anxiety or dissatisfaction.

Comprehensive protocol

The comprehensive protocol was developed using previous guidelines for HIV counselling in pregnancy as a basis^{18,25} and with help and feedback from two specialist HIV counsellors, from Edinburgh and London (see below for details).

The comprehensive discussion protocol incorporated a number of information points which the midwife discussed with everyone in this group, including:

- why HIV testing is offered in pregnancy
- HIV infection and transmission
- the HIV test and what the results mean
- the benefits and disadvantages of testing and insurance details.

If the woman then decided to take the test, there was a second list of points to discuss including:

- personal risk factors (if the woman chose to discuss any)
- planning the possibility of a positive result
- the support available if positive
- what the test involves and how the result is given.

At the end of both parts of the protocol the woman was asked if she wished to be tested.

Minimal protocol

The minimal counselling protocol was a simple check that the woman had read and understood the leaflet and to ask whether she had any questions about it. She was then asked if she wanted the test. At this stage, if the woman did not want the test the midwife did not discuss the test further. If the woman did seem interested in the test, she was asked if she understood what a positive result and a negative result implied. If she was not clear about this, the midwife would explain the meaning of the result, including details about the window period. She was then given information about the procedures for taking the test and how both positive and negative results would be given.

The midwives were given the draft protocols to read. During the training they offered feedback regarding any problems they could foresee with the wording and style. These comments were incorporated into a second draft which was used for the first few weeks of the trial. During those first few weeks, a number of issues arose, mainly regarding the wording and the ordering of the comprehensive protocol. The midwives also felt that they needed more help in knowing how to broach the subject. Taking into account these problems, the final comprehensive protocol was devised, which is reproduced in appendix 6.

Both protocols were printed on card and were available in each consulting room for the midwives' easy reference.

Main sources of help and feedback

- Beverly Cummins, HIV Specialist Counsellor, City Hospital, Edinburgh.
- Carolyn Walker, HIV Specialist Counsellor, Newham Healthcare NHS Trust, Women's Services.

Chapter 5

Outcome measures

Booking questionnaire development

The development of the first questionnaire for pregnant women, 'Booking questionnaire', as shown in appendix 7, will be described in some detail below. The final version of the questionnaire was developed with input from each of the authors and the midwives in the clinic. All the scales were piloted among a group of pregnant women to check readability, ambiguities, anything relevant missing and length of time required to complete. On average, women took between 5 and 10 minutes to complete the questionnaire.

Knowledge of HIV

The knowledge measure was devised for this study, based on ideas from various previous studies investigating knowledge of HIV. There were 11 statements, including nine items of general knowledge about HIV infection and transmission, for example: 'A person can be infected with HIV and look well'; 'If someone gets a positive HIV test result, it means they have AIDS'. There were also two specific items relating to HIV in pregnancy, for example 'A pregnant woman who has HIV can infect her baby through breastfeeding'. For each statement, the woman was asked to tick 'agree', 'disagree' or 'unsure'. The internal reliability of the scale was low (Cronbach's $\alpha = 0.46$) and so each item was treated separately.

Knowledge of antenatal tests

We used a scale derived from previous work by Marteau and colleagues,²⁶ but adapted slightly to include two items on CF testing which is offered routinely in this setting. The first section (knowledge of tests done) gave a list of 11 tests, including HIV, that are available in the clinic, some of which are routine (e.g. rubella), and some of which are not (e.g. toxoplasmosis). The woman was asked to tick whether she had had the test, had not had the test, or didn't know. The second section (comprehension of tests) consisted of seven questions (e.g. 'When you give a urine sample at the clinic, what is it routinely tested for?') each with four multiple choice answers (e.g. 'protein', 'how old the baby is', 'twins', 'don't know'). Knowledge scores were developed for each of the two sections by totalling the number of correct answers for each subject.

However, for the first section (knowledge of tests done), the score was calculated only for the four routine tests, since for the other tests it was not easy to determine for each participant whether the test had actually been performed or not.

Anxiety

Anxiety was measured using a standardised, short form of the Spielberger State Trait Anxiety Inventory (STAI) developed by Marteau and Bekker.²⁷ The scale has six items (e.g. 'I feel calm', 'I am tense'), each with a four-point response scale ranging from 'not at all' to 'very much'. The internal consistency of the scale was assessed using our sample and found to be high (Cronbach's $\alpha = 0.89$). An anxiety score was computed by adding up the responses to all six items, re-coding the low anxiety items (e.g. 'I am calm') in reverse order, so that a high score indicated high anxiety. The score (out of 24) was then pro-rated to correspond to the original 20-item scale (out of 80), so that it was comparable with previous studies.

Satisfaction

The satisfaction scale was developed specifically for the purposes of this study. There were seven items relating to the woman's experience at the clinic (e.g. 'The length of time you spent with the midwife was ...'). Each statement had a five-point response scale: 'poor', 'satisfactory', 'good', 'very good' or 'excellent'. The first and last items were not included in the final scale because they were not related directly to satisfaction with the consultation with the midwife, which was our main interest. Moreover, they reduced the internal reliability of the scale. The final, five-item scale had a high internal reliability (Cronbach's $\alpha = 0.92$).

Attitudes towards pregnancy

We used two scales, derived from work by Reading and colleagues²⁸ and used by Marteau and colleagues.²⁶ One of the scales related to attitudes towards the pregnancy and the other to attitudes towards the baby. The questions asked were: 'How do you feel **now** about being pregnant?' and 'How do you feel **now** about the baby?'. Each scale consisted of seven adverbs relating to these questions (e.g. 'fulfilled', 'stressed' (pregnancy) and 'maternal', 'concerned' (baby)), each with a five-point response scale ranging from 'not at all'

to 'very much'. The internal consistency of the two scales was assessed using our sample and found to be reasonable if 'optimistic' was removed from the pregnancy scale (Cronbach's $\alpha = 0.73$) and if concerned was deleted from the baby scale (Cronbach's $\alpha = 0.79$). Two attitude scores were computed by adding up the responses to the six remaining items for each scale, re-coding the negative attitude items (e.g. 'stressed') in reverse order, so that a high score indicated a positive attitude.

Perceived benefits of testing

Perceived benefits of the test were measured using items adapted from previous work by Meadows and colleagues.²³ The women were asked the question 'How much benefit do you think the HIV test is ... for the baby, for research, for the mother and for the midwives?'. Each of these four parts of the question had a five-point response scale ranging from 'no benefit' to 'great benefit'. The internal consistency of the scale was not particularly good (Cronbach's $\alpha = 0.63$), and so the four items were treated separately in the analyses.

Attitude to the offer of testing

Women were asked if they were in favour of the HIV test being made available to pregnant women by giving a choice of response of 'yes', 'no' or 'unsure'. They were then asked to tick a statement to define what they thought was the best way of offering the HIV test to pregnant women. They were given a choice of five methods, including 'Send information leaflet then short, pre-test discussion with the midwife (up to 5 minutes)', 'Do the test routinely like the test for rubella, without discussing it' or 'Don't know'.

Perceived risk

Women were asked to rate how likely they thought it was that they were infected with HIV on a five-point response scale from 'very likely' to 'very unlikely'.

Reason for testing/not testing

Two checklists were developed, based on checklists used in a previous survey by Meadows and Catalan²⁹ and incorporating other reasons volunteered by the participants in this previous survey.

Those who had taken the test were given a selection of nine possible reasons (e.g. 'I was concerned about risks to the baby'; 'It's a good idea to have as a routine test') and were asked to tick two boxes to indicate their two most important reasons for taking the test. Those who had chosen not to take the test were given a selection of 13 possible

reasons (e.g. 'I would rather not know if I'm positive'; 'I've been in a stable relationship for a long time') and were also asked to tick two boxes.

Follow-up questionnaire development

The development of the follow-up questionnaire for pregnant women, 'Return visit questionnaire', as shown in appendix 9 will be described in some detail below. Again the final version of the questionnaire was developed with input from each of the authors and the midwives in the clinic and all of the scales were piloted among a group of pregnant women. On average, women took 5 minutes to complete this questionnaire.

Anxiety and reassurance about specific antenatal tests

Seven questions were asked concerning anxiety and reassurance about the commonly used antenatal screening tests (ultrasound, couple CF status, immunity to rubella, α -foetoprotein (AFP), syphilis, full blood count and blood grouping). These questions were derived from work by Sherr and colleagues.¹⁴ The anxiety part of the scale was validated³⁰ using a group of 120 pregnant women at the antenatal clinic by correlating their responses with the standardised six-item form of the STAI.²⁷ The correlation was positive and significant ($r = 0.44$, $p < 0.01$) suggesting that the scale was a valid measure of anxiety. Our main aim was to measure the anxiety and reassurance in relation to HIV testing in comparison with the other antenatal tests, so the items were treated separately.

The value of HIV testing

The value of HIV testing in relation to other tests was measured by asking women to rate five tests (HIV, scan, AFP, CF and rubella) in order of personal importance, from 1 (most important) to 5 (least important).

Anxiety and attitudes towards pregnancy

These outcomes were measured using the scales used in the 'Booking questionnaire' as described earlier in this chapter.

Satisfaction with method of receiving HIV test result

Women were asked to complete this section if they had chosen to take the HIV test. They were asked if they had received their result within a week and if they were satisfied with the way the result was given.

Midwives' checklist

The midwives completed a checklist for each woman they consulted (appendix 9). They noted their own personal code, so that we could identify the uptake rates associated with each midwife. The midwives also noted the following:

- the time they started and finished talking about HIV testing
- whether the woman took the HIV test and signed the consent form
- whether the woman's partner was present
- whether the woman or her partner had had a previous test
- whether the woman or any previous partner was or had been an intravenous drug user
- nationality if English was not the woman's first language.

Chapter 6

Participants

Obtained sample

Over the 10-month period, 3505 pregnant women were randomised and a total of 3024 women participated (see *Table 4*). Reasons for exclusion (following randomisation) were as follows: known HIV positive status ($n = 1$); poor English, with either no interpreter available or in cases in which the interpreter felt it was inappropriate to discuss HIV testing ($n = 6$, comprising two Pakistanis, two Chinese, one Russian and one Italian). Reasons for not participating were: miscarriages or terminations before booking ($n = 311$); not receiving study information through the post ($n = 33$); never attending the clinic ($n = 119$); refusal to participate ($n = 11$).

Thirty-five women were defined as being at high risk of HIV due to either their own or a partner's intravenous drug user status. Although these women were all randomised into the study, they were treated as they would have been before the study began, regardless of intervention group (i.e. the 'high-risk' women were all selectively offered the test).

The response rate to the 'Booking questionnaire' which measured the main outcomes was 89%

(2704/3024). Response rates did not differ by intervention group as shown in *Table 4*.

Approximately half of the women in the sample were eligible to complete the 'Return visit questionnaire' at 32 weeks of pregnancy. This was due to time constraints of the study in the clinic, so that at the end of the 10-month study period, distribution of the 'Return visit questionnaire' was also stopped. Therefore, since most women book at around 12 weeks of pregnancy, we were not able to approach for follow-up women booking in the final 20 weeks of the trial. Moreover, the aim of this second questionnaire was to provide follow-up and additional information – it did not include any of the main outcome measures. Also, women were only approached to fill in the 'Return visit questionnaire' if they had completed the first questionnaire, because we aimed to follow up the responses of the same women. There were also administrative difficulties in keeping track of return appointment times and missing the chance to approach women because they spent less time in the waiting room before being called in for their appointment. Twenty-nine women refused to complete the questionnaire when approached. In all, 788 out of 2704 women completed the 'Return visit questionnaire', and these women were fairly evenly distributed across the intervention groups.

TABLE 4 Study groups, target sample size, actual number of participants and response rates

Group	Leaflet	Discussion with midwife	Offered testing?	Target sample size	Number of participants*	Number (%) who completed questionnaire
1	None	None	No [†]	1000	994	882 (89)
2	'All blood tests'	Minimal	Yes	500	495	441 (89)
3	'All blood tests'	Comprehensive	Yes	500	521	478 (92)
4	'HIV-specific'	Minimal	Yes	500	495	453 (92)
5	'HIV-specific'	Comprehensive	Yes	500	519	450 (87)
Total				3000	3024	2704 (89)

* These figures represent all those who were randomised and participated in the trial, all of whom were analysed for the primary endpoint (uptake rate)
[†] HIV testing was available on request for this group and was advertised in a letter about the study sent to all women and by poster in the clinic

Demographic variables

Data on demographic variables were downloaded from the hospital computer. Because information on risk behaviour and data on perception of risk were not collected in this study, the known HIV prevalence in the area of Edinburgh in which women lived was used as an indirect measure of risk. A five-point 'area risk' code (in which 1 = no HIV cases in area and 5 = > 10 cases per 10,000) was derived on the basis of the number of identified HIV-infected persons alive in each postcode area to the end of 1996 (excluding homosexual

and bisexual males).³¹ A seven-point social deprivation score was also derived from postcodes and used as a measure of affluence and deprivation in which 1 = highly affluent and 7 = very deprived.³² Because data from the hospital computer were incomplete, there were some missing data for the demographic variables, resulting in different total sample sizes.

There were no significant differences in any demographic factors between the five intervention groups (*Table 5*) which indicates that the groups were comparable.

TABLE 5 A comparison of demographic variables between intervention groups

Demographic variable	Group 1	Group 2	Group 3	Group 4	Group 5	Significance test
Mean (SD) age (years)	29.3 (5.4)	29.4 (5.3)	29.8 (5.5)	29.6 (5.5)	29.6 (5.5)	$F_{4,3009} = 0.89, p = 0.47$
Marital status (% married)	67.9	73.3	72.7	72.3	69.4	$\chi^2 = 7.3, df = 4, p = 0.12$
Parity (% primiparous)	52.1	48.0	44.8	48.8	48.3	$\chi^2 = 7.9, df = 4, p = 0.10$
Employment status (% unemployed)	7.7	7.1	6.5	6.2	7.2	$\chi^2 = 1.2, df = 4, p = 0.87$
Area risk code (% lower risk) [*]	41.8	39.8	42.1	41.9	42.4	$\chi^2 = 0.8, df = 4, p = 0.94$
Social deprivation score (% affluent) [†]	56.7	54.2	51.6	54.8	54.6	$\chi^2 = 3.2, df = 4, p = 0.52$
<p>[*] The area risk codes were split into two groups for the purpose of this presentation of the data. The lower risk group includes groups 1, 2 and 3 of the five categories</p> <p>[†] The social deprivation scores were split into two groups for this presentation of the data. The affluent group contains groups 1, 2 and 3 of the seven categories</p>						

Chapter 7

Uptake of HIV testing

Uptake of testing by intervention group

Table 6 shows the uptake rates for each of the five study groups. The average uptake for all women offered the test (excluding the control group) was 35%. Each of the methods of directly offering the test resulted in a higher uptake than in the control group (5.5% uptake) ($\chi^2 = 308.5$, $df = 4$, $p < 0.0001$). However, there was no significant difference between the four methods of directly offering the test ($\chi^2 = 3.9$, $df = 3$, $p = 0.27$).

Detection of HIV-positive status

Of the 760 women tested during the trial, one woman was newly identified as HIV positive. Due to our linkage with the anonymous Guthrie sampling survey (see chapter 2 for details), we know that there were three further HIV-positive women in the sample who were undetected during the trial. Two of these women were in the control group and one was in an intervention group. Thus, in this study period, a detection rate of one in four (i.e. 25%) previously undiagnosed infections was obtained.

Predictors of uptake

Univariate analyses

Table 6 presents the univariate results for the predictors of uptake. Chi-squared tests were used to compare proportions of women taking the test, using the Mantel–Haenszel chi-squared test for ordinal data.

Demographic factors

Those who were significantly more likely to take the HIV test were: younger women (aged < 30 years); unmarried women; unemployed women; women who lived in more socially deprived areas. Parity had no effect on uptake: women who were having their first baby were not more or less likely to take the test. Also, area risk score had no effect on uptake: women who lived in areas of the city which had a high incidence of HIV infection were not more or less likely to take the test than those who lived in areas of low incidence.

TABLE 6 The effect of the intervention, demographic and other factors on uptake: univariate analyses

Variable	No. (%) taking HIV test	Significance test
Intervention		$\chi^2 = 308.5^{***}$
1	55/994 (5.5)	
2	179/495 (36.2)	
3	193/521 (37.0)	
4	171/495 (34.5)	
5	164/519 (31.6)	
Age		$\chi^2 = 6.97^{**}$
Older (≥ 30 years)	367/1579 (23.2)	
Younger (< 30 years)	393/1433 (27.4)	
Marital status		$\chi^2 = 28.9^{***}$
Married	468/2095 (22.3)	
Unmarried	277/873 (31.7)	
Parity		$\chi^2 = 0.75$
Multiparous	377/1536 (24.6)	
Primiparous	382/1474 (25.8)	
Employment status		$\chi^2 = 15.3^{***}$
Employed + housewife	574/2367 (24.2)	
Unemployed	67/179 (37.4)	
Area risk code[†]		MH $\chi^2 = 0.32$
1	48/173 (28)	
2	158/692 (23)	
3	87/352 (25)	
4	261/954 (27)	
5	184/751 (25)	
Social deprivation score[‡]		MH $\chi^2 = 7.8^{**}$
1	108/490 (22)	
2	112/509 (22)	
3	98/402 (24)	
4	208/828 (25)	
5	33/144 (23)	
6	28/94 (30)	
7	33/93 (35)	
** $p < 0.01$; *** $p < 0.001$		
MH, Mantel–Haenszel		
[†] In Group 1 there are no HIV cases in the total population for the postcode areas included, whereas in Group 5 the rate is > 1 per 1000 (see chapter 6 for further details)		
[‡] Score 1 = highly affluent and score 7 = very deprived (see chapter 6 for further details)		
		continued

TABLE 6 contd The effect of the intervention, demographic and other factors on uptake: univariate analyses

Variable	No. (%) taking HIV test	Significance test
Midwife		$\chi^2 = 100.2^{***}$
A	52/353 (15)	
B	21/134 (16)	
C	55/316 (17)	
D	66/138 (48)	
E	68/312 (22)	
F	41/170 (24)	
G	138/492 (28)	
H	78/263 (30)	
I	61/188 (32)	
J	119/361 (33)	
K [†]	63/291 (22)	
Partner's presence		$\chi^2 = 1.04$
Present	399/1524 (26.2)	
Absent	360/1466 (24.6)	
Previous test		$\chi^2 = 49.4^{***}$
Previously tested	131/298 (44)	
Not previously tested	596/2402 (25)	
*** $p < 0.001$ MH, Mantel-Haenszel		
[†] This midwife code represents a combination of ten midwives who were not analysed individually as they each did fewer than 63 bookings. The ten core midwives each did more than 130 bookings		

Situational factors and previous behaviour

There were significantly different uptake rates, ranging from 15% to 48%, among the ten core midwives. Women who had previously been tested for HIV were significantly more likely to take the

test. However, women whose partner was present when they were offered the test were no more or less likely to take the test than those whose partner was absent.

Perceived risk

The majority of women stated that it was 'very unlikely' that they were infected with HIV ($n = 2307$). The five-point scale was thus re-coded into a dichotomous variable indicating either 'no risk' (point 5) or 'some to high risk' (points 1–4). Women who thought there was some to high risk of being infected were more likely to take the test (104/340, 31% uptake) than women who perceived no risk (578/2307, 25%) ($\chi^2 = 4.74$, $df = 1$, $p = 0.03$).

Multivariate analyses

Table 7 presents the multivariate predictors from logistic regression analyses, using a forward conditional method of entry into the model. The Wald chi-squared is produced by the SPSS logistic regression program to indicate the independent significance of each of the variables in the model. Odds ratios and 95% confidence intervals were calculated using the beta values obtained by the program. All variables that were significant at the univariate level were entered into the model, apart from perceived risk because that was a questionnaire measure and its inclusion would have reduced the total number included in the model. It was also measured after booking and could therefore not be usefully described as a predictor of uptake. Since there was no significant difference between the different methods of offering the test, but there was an effect of being offered the test compared with the control, a new variable was computed called 'offered testing',

TABLE 7 Logistic regression analyses (forward conditional method): statistically significant predictors of uptake of HIV testing

Predictor of uptake	Uptake of HIV testing			
	Wald χ^2	df	p value	Odds ratio of uptake* (95% confidence interval)
Offered testing	186.8	1	0.0000	8.4 (6.2–11.5)
Midwife	84.3	10	0.0000	–
Marital status	20.9	1	0.0000	0.59 (0.46–0.74)
Previous test	11.5	1	0.0007	1.6 (1.2–2.1)
Age	6.6	1	0.01	0.98 (0.96–0.99)

* Odds ratios were calculated for being offered testing directly versus being in the control group, for being married as opposed to being single, for having had a previous test versus not having had a previous test and for an increase in age. A single odds ratio cannot be calculated for the overall effect of all the midwives

which split the sample in two: control group and intervention groups. The best independent predictor of uptake was being directly offered the test, followed by which midwife offered the test, not being married, having had a previous test, and finally, being younger. Although deprivation score and employment status were related to uptake (*Table 6*), they were not significant independent predictors.

Demographic sub-group analyses

Older women (aged ≥ 30 years) were more likely to take the test when sent the 'all blood tests' leaflet (36% uptake) than when sent the 'HIV-specific' leaflet (28% uptake). There was no difference in uptake according to leaflet received for the younger women (37% with the 'all blood tests' leaflet versus 39% with the 'HIV-specific' leaflet).

A significant interaction between age and intervention group on uptake was found using logistic regression (Wald $\chi^2 = 5.44$, $df = 1$, $p = 0.02$). There was no interaction between intervention group and area risk score, social deprivation score, marital status, employment status or parity. That is, no one method emerged as the most successful in achieving uptake within any of the other demographic sub-groups within the sample (e.g. deprived versus affluent or married versus unmarried).

Summary and discussion

Offering the test to all women resulted in significantly higher uptake (35%) when compared with the 'on request' availability open to the control group (5.5%).

The control group was necessary for methodological reasons, but raised important ethical issues. For the study to be acceptable to the Ethics Committee and to the patient representative groups we contacted, we had to make it clear to the control group that the trial was taking place and that they could ask for an HIV test. In response to this, there was an increase in testing from less than 1% (pre-trial rate) to 5.5%, and thus more women in this group had testing than would otherwise have done.

It should be noted that although the uptake was much lower than expected for the sample size calculation, the power to detect differences between groups is unchanged. The expected uptake rate was based on the findings of a previous study in Edinburgh which found an uptake rate of 71%.³³ The large difference in uptake rate between

the two studies is perhaps a reflection of the way the test was presented. Whereas the previous study emphasised the research purpose of determining HIV prevalence, the present study was geared towards women's choice rather than a deliberate aim to increase testing rates.

No one method of offering the test emerged as the most effective, which suggests that it does not matter how the test is offered, as long as it is offered. Previous research on prenatal CF testing has suggested¹² that more information results in lower uptake, but this is not supported by our findings.

In an attempt to explain uptake, demographic and situational predictors of uptake were assessed. Being unmarried and younger were multivariate demographic predictors suggesting that women were making the decision to test based on personal risk assessment. The univariate finding that uptake increased with extent of deprivation supports this assertion, as does the association between perceived risk and uptake. However, there was no effect of risk area on uptake suggesting that women at higher risk in terms of possible local exposure to the virus were no more likely to take the test than women at very low risk. The data suggest that the 'all blood tests' leaflet was more effective in encouraging the older women to take the test which may reflect older women's lower perceived risk and thus their reluctance to read a leaflet which they perceive as personally irrelevant (the 'HIV-specific' leaflet). However, as age was one of six demographic variables considered for interaction with method, this result may have arisen by chance as the result of multiple testing and should be regarded with caution.

The midwife had a very important effect on uptake. This supports the findings of a smaller study ($n = 448$) by Meadows and colleagues³⁴ which recorded much wider differences between 12 midwives (uptake rates ranging from 3% to 82%). The suggestion by Meadows and colleagues³⁴ that the difference could be explained by the midwives' counselling approach has not been supported by the data in our study as midwives in the present study all followed the same protocols and there was no interaction effect between midwife and intervention group. Our data provide clear evidence that giving the midwives the same information during training and clear written protocols to work from does not necessarily result in their acting in exactly the same way. This challenges the prevalent assumption that the behaviour of health professionals is based

solely on the extent of their medical knowledge. Marteau and Johnston³⁵ have argued that psychological models used to predict patient behaviour should also be applied to health professionals, implying that midwives' attitudes should be taken into account when considering patients' uptake.

Our focus was on women's choice and the aim described in this chapter was to determine uptake rates. Nevertheless, the main point of offering HIV testing is to enable infected women to take steps to prevent vertical transmission. The prevalence, shown by anonymised testing, was similar to that in previous years (1 in 600 deliveries). What was unexpected and quite out of keeping with past experience,⁶ was the high proportion of infected women for whom seropositivity was unknown. During the study, one HIV-positive woman was detected out of two who were offered the test. Two unknown positive women in the control group did not request testing, which reinforces the case for offering the test, rather than simply making it available. Whether another voluntary

system would be more effective is not certain. Out of 35 women selectively offered testing because of a history of injecting drug use (self and/or partner), 14 declined HIV testing. Considering these 14 women in more detail, eight reported having had a previous test which may or may not have been recent, which leaves six women at high risk untested, to our knowledge. From comments written by the midwife on five of these women's checklists we know that three of the women were willing to discuss testing, but one just did not accept the test, one could not face knowing her status and one wished to think about it. The other two women were adamant that they did not wish the test and did not even want to discuss it. Whatever the type of testing programme that is adopted, apart from a mandatory programme which would be undesirable and illegal,³⁶ women retain the right to refuse testing and thus women at high risk may be missed. Routine ('opt-out') testing for all women **may** provide an easier environment for women at high risk to accept testing without feeling they are being singled out, but this will have to be assessed (see annex, page 81).

Chapter 8

Acceptability of testing – main outcomes

Statistical analysis was done using SPSS; all analyses were by intention to treat.

Knowledge of HIV

A description of the responses to the HIV knowledge items for the entire sample is presented in *Table 8*. General knowledge of HIV was fairly good, but there was a great deal of uncertainty and even misconception about the specific items relating to preventing HIV transmission from mother to baby. This specific information was provided only in the ‘HIV-specific’ leaflet and the comprehensive discussion protocol.

To compare the effect of the interventions, HIV knowledge was analysed by the chi-squared test to compare the proportion who made the correct response with those who made an incorrect or ‘don’t know’ response for each item separately. There were no differences between the five intervention groups in the extent of correct responses for any of the general knowledge items. However, there was a significant difference between groups on both of the specific knowledge items, as shown

in *Table 9*. Specific knowledge was greatest when the information was repeated in both the leaflet and the discussion (‘HIV-specific’ leaflet and comprehensive discussion group).

Knowledge of antenatal tests

A description of the responses to the antenatal knowledge items for the entire sample is presented in *Table 10*. There was a reasonable level of misconception and uncertainty about the routine tests, particularly about rubella and syphilis testing. There was a great deal of uncertainty about whether or not non-routine tests had been done.

For the multiple-choice component relating to test comprehension (*Table 11*), there was a high level of knowledge for most items, although there was a high level of uncertainty and misconception for the CF item.

To compare the effect of the interventions, antenatal test knowledge was analysed by the Kruskal–Wallis chi-squared test to compare the mean number correct for both sections. The

TABLE 8 HIV knowledge (specific and general): description of sample

Questionnaire item*	Correct (n)	Incorrect (n)	Unsure (n)
Reduce infection to baby by taking AZT	819	173	1675
Can infect baby by breastfeeding	1186	409	1067
Positive HIV test means AIDS	2392	165	116
HIV is virus which causes AIDS	2456	94	126
Can be infected and look well	2552	25	95
Infection by kissing	2511	60	98
Infection by unprotected sex	2655	9	14
Infection by blood donation	2202	325	143
Infection by mosquito bite	1592	350	717
Infection by sharing needles for drug injecting	2677	3	5
Infection by being in swimming pool	2603	5	72

* See appendix 7

TABLE 9 Specific knowledge about HIV by method of offering the test

Group	Leaflet	Discussion with midwife	Breastfeeding knowledge [†] : no. (%) correct	AZT knowledge [‡] : no. (%) correct
1	None	None	263/865 (30)	128/865 (15)
2	'All blood tests'	Minimal	128/435 (29)	87/438 (20)
3	'All blood tests'	Comprehensive	284/468 (61)	190/470 (40)
4	'HIV-specific'	Minimal	202/448 (45)	171/448 (38)
5	'HIV-specific'	Comprehensive	309/446 (69)	243/446 (54)
Significance			$\chi^2 = 267.4$, df = 4 ^{***}	$\chi^2 = 277.8$, df = 4 ^{***}
*** p < 0.001				
[†] This refers to the item 'a pregnant woman who has HIV can infect her baby through breastfeeding' (see appendix 7)				
[‡] This refers to the item 'a pregnant woman who has HIV can reduce the chance of her baby becoming infected by taking zidovudine (AZT)' (see appendix 7)				

TABLE 10 Knowledge of tests done at the antenatal clinic*: description of sample

Type of test	Name of test	Yes	No	Unsure
Choice	AFP	835	1425	116
	HIV	696	1688	71
	CF	1637	821	76
Routine	Scan	2617	62	4
	Rubella	1830	534	142
	Blood group	2136	221	205
	Syphilis	1749	383	382
Non-routine	Chorionic villus sampling	102	1305	856
	Amniocentesis	108	1930	285
	Hepatitis B	485	1060	811
	Toxoplasmosis	218	1107	1019

* See the booking visit questionnaire reproduced in appendix 7

results are presented in Table 12. For knowledge about which tests were done (including only routine tests) there was a significant difference between the intervention groups. Clearly, the two groups receiving the 'all blood tests' leaflet had more knowledge than either the control group or those who had received the 'HIV-specific' leaflet. Comprehension of tests did not differ by intervention group.

Overall, knowledge about antenatal tests was fairly good. The 'all blood tests' leaflet improved knowledge about the routine blood tests done at the clinic. More importantly, there seemed to be no effect of offering HIV testing on the retention of other antenatal information.

TABLE 11 Comprehension of tests at antenatal clinic: description of sample

Question*	Correct (n)	Incorrect (n)	Don't know (n)
What is urine tested for?	2319	17	331
What is amniocentesis for?	2338	38	290
What is the main use of the scan?	2675	5	11
Result of spina bifida test	2277	199	155
When is spina bifida test done?	2570	11	106
What is mouthwash tested for?	2580	15	86
CF risk	1675	330	666

* See the booking visit questionnaire reproduced in appendix 7

TABLE 12 Mean antenatal knowledge scores by intervention group

Intervention group	Tests done: mean (SD) no. correct	Comprehension of tests: mean (SD) no. correct
1	3.0 (1.1)	6.1 (1.2)
2	3.2 (1.1)	6.1 (1.1)
3	3.2 (1.0)	6.1 (1.1)
4	3.0 (1.1)	6.0 (1.3)
5	3.0 (1.1)	6.0 (1.3)
Significance	KW $\chi^2 = 10.4^*$	KW $\chi^2 = 1.98$ NS
KW, Kruskal–Wallis		
* p < 0.05; NS, not significant		

Anxiety

Anxiety at booking

The anxiety level of the entire sample (pro-rated mean = 36.7, standard deviation (SD) = 11.0, maximum score possible is 80) is very similar to that found previously in a group of 200 normal pregnant women (mean = 37.1, SD = 11.0) which is lower than that found in a group of women after receiving an abnormal screening result for foetal abnormality (mean = 47.7, SD = 15.8).²⁷

The mean anxiety scores were compared across intervention groups (including controls) using one-way analyses of variance (*Table 13*). Anxiety was not affected by method of offering testing ($F_{4,2568} = 1.38, p = 0.24$).

Anxiety at follow-up

The anxiety level of the entire sample at follow-up was higher than that at booking (pro-rated mean = 39.0, SD = 11.0; within-subjects $t_{723} = 5.99, p < 0.001$).

The mean anxiety scores at follow-up were compared across intervention groups (including controls) using one-way analyses of variance. Anxiety at follow-up was not affected by method of offering testing ($F_{4,723} = 1.11, p = 0.35$).

Since there was an increase in anxiety between booking and follow-up, we examined the data to see if the change differed by intervention group (i.e. did one method of offering testing increase anxiety more than other methods?). Mean anxiety scores at Time 2 were compared across groups using analyses of variance, including anxiety at Time 1 as a covariate. There was no effect of method of offering testing on anxiety over time ($F = 0.61, p = 0.66$).

Satisfaction

Satisfaction with the consultation, in general, was high (mean score = 21.5, SD = 3.4, maximum score possible = 25). Satisfaction was compared across intervention groups (including the controls) by using non-parametric analysis of variance (Kruskal–Wallis) because of the negatively skewed distribution (*Table 13*). Satisfaction was not affected by the method of offering testing (Kruskal–Wallis $\chi^2 = 2.23, df = 4, p = 0.69$).

Attitudes towards pregnancy

Attitudes towards pregnancy were generally positive (mean score = 24.1, SD = 4.0, maximum score possible = 30) as were attitudes towards the baby (mean score = 24.1, SD = 4.3, maximum score possible = 30). Both attitude scales were compared across intervention groups (including the controls) by using non-parametric analysis of variance (Kruskal–Wallis) because of the negatively skewed distributions (*Table 13*). Neither attitudes towards pregnancy (Kruskal–Wallis $\chi^2 = 7.41, df = 4, p = 0.12$) nor attitudes towards the baby (Kruskal–Wallis $\chi^2 = 3.39, df = 4, p = 0.50$) were affected by the method of offering testing.

Perceived benefits of testing

In general, women were very positive about the benefits of testing for the baby (mean = 4.47, SD = 0.94, maximum score possible = 5), the midwife (mean = 4.17, SD = 1.13), the mother (mean = 4.27, SD = 0.99), and research (mean = 4.31, SD = 0.93). Each of the four perceived benefits items was compared across intervention

TABLE 13 Univariate analyses for anxiety, satisfaction and attitudes towards pregnancy and baby*

Intervention group	Mean (SD) score for:			
	Anxiety [†]	Satisfaction	Attitudes towards baby	Attitudes towards pregnancy
1	11.0 (3.2)	21.5 (3.4)	23.9 (4.2)	24.1 (3.9)
2	10.8 (3.5)	21.6 (3.3)	24.3 (4.2)	24.5 (3.9)
3	10.8 (3.0)	21.4 (3.2)	24.3 (4.2)	24.1 (3.9)
4	11.0 (3.4)	21.4 (3.5)	24.0 (4.3)	24.0 (4.1)
5	11.1 (3.3)	21.7 (3.3)	24.0 (4.5)	23.9 (4.1)
Significance	NS	NS	NS	NS

* See the booking visit questionnaire reproduced in appendix 7
[†] These means are not pro-rated; the maximum score is 24

groups (including the controls) by using non-parametric analysis of variance (Kruskal–Wallis) because of the negatively skewed distributions. There was a significant effect of intervention group on perceived benefits for the baby (Kruskal–Wallis $\chi^2 = 30.27$, $df = 4$, $p < 0.0001$). Investigating this difference further, by comparing just the different discussion interventions, it was found that the comprehensive discussion group perceived significantly more benefits for the baby (mean rank = 1388) than either the minimal discussion group (mean rank = 1268) or the control group (mean rank = 1249) (Kruskal–Wallis $\chi^2 = 27.8$, $df = 2$, $p < 0.0001$). Comparing just the different leaflet interventions, it was found that both leaflet groups (mean rank = 1326 for ‘all blood tests’ leaflet; mean rank = 1333 for ‘HIV-specific’ leaflet) perceived significantly more benefits than the control group (mean rank = 1249) (Kruskal–Wallis $\chi^2 = 10.03$, $df = 2$, $p < 0.01$). So both leaflets were equally more successful than the control group in conveying benefits of testing for the baby. However, comprehensive discussion was more successful than minimal discussion.

There was no effect of the intervention on any of the three remaining perceived benefits items.

Summary and discussion

In comparison with the control group, offering the test to all women did not increase anxiety or dissatisfaction. Neither did it affect the women’s attitudes towards their pregnancy or their retention of other antenatal information. Overall, the concerns of many health carers that the universal

offer of testing would be intrusive, would cause anxiety or would adversely affect the antenatal consultation have not been sustained.

The method of offering the test had no effect on anxiety (at booking or at follow-up). Although anxiety increased overall over time, this increase was the same for all groups and may have reflected increasing anxiety as delivery approached. Nor did the method of offering testing have any effect on women’s satisfaction, their attitudes towards their pregnancy or their retention of other antenatal information. These results lend no support to previous suggestions that comprehensive discussion may have an adverse impact.¹¹

However, knowledge of the benefits of testing increased with amount of information given. Also perceived benefits were greater in those who received either of the leaflets and the comprehensive discussion. Firstly, this is a clear indication that the midwives followed the discussion protocols and that the interventions were indeed systematically different, thus validating the study design. Secondly, it suggests that providing **specific** information about the benefits of testing not only can increase the likelihood of women making an informed choice, but also can increase the perception of the benefits of testing, which is likely to increase uptake. So, although prolonged discussion along the lines of the clinic model for HIV testing seems unnecessary, specific benefits should, nonetheless, be highlighted. Women’s **general** knowledge about HIV was good, whether or not they were given information. Providing **general** information about HIV is unlikely, therefore, to be useful for most women.

Chapter 9

Further issues of acceptability

Are pregnant women in favour of HIV testing in pregnancy?

Of those who completed the questionnaire, 2362 (88%) women responded positively to the question 'Are you in favour of an HIV test being available to all pregnant women?' Seventy-nine women (3%) said 'no' and 236 (9%) were unsure.

What do pregnant women think is the best way to offer the test?

The frequencies of responses for all five possible methods are presented in *Table 14*. Of those women who were in favour of the test being available, the method that was most frequently ticked as the best method was 'send information leaflet, then short, pre-test discussion with the midwife (up to 5 minutes)'. Notably only 210 women (9%) reported that it should be left up to the woman to ask the midwife if she wants a test ('on request' method). A small number ($n = 76$, 3%) responded that they thought the test should be routine without discussion. However, this item was only added after 5 months of the study when we realised that some women felt this way.

What reasons do women give for taking and not taking the test?

The most frequently given reason for taking the HIV test was 'it's a good idea to have as a routine test',

followed by 'to help research' and then 'I was concerned about risks to the baby'. Very few women reported that they had taken the test because they were at risk of infection. Also, hardly anyone reported that they had felt advised by a midwife, doctor or friends and family to take the test (*Table 15*).

The most frequently given reason for not taking the HIV test was 'I've been in a stable relationship for a long time' followed by 'I'm not in a high-risk

TABLE 15 Reasons for taking the HIV test: description of sample

Reason	Number of women*
I was concerned about risks to the baby	305
I was concerned about my own health	132
I am/have been at risk of infection	27
I was persuaded by family and/or friends	8
My doctor thought it was a good idea	5
A midwife advised me to	12
To help research	322
Because it was offered	218
It's a good idea to have it as a routine test	462

* Women who took the test were asked to select two reasons from the list; see appendix 7

TABLE 14 Set responses to the question 'What do you think is the best way of offering the HIV test to pregnant women?'

Set response*	No. (%) with response
Send information leaflet then ask women if she wants test or not at the clinic	454 (18)
Send information leaflet, then short, pre-test discussion with the midwife (up to 5 minutes)	1203 (48)
Send information leaflet, then long, pre-test discussion with the midwife (up to 15 minutes)	454 (18)
Do the test routinely like the test for rubella, without discussing it [†]	76 (3)
Leave it up to the women to ask the midwife if she wants the test	210 (8)
Don't know	67 (3)
Other	20 (1)

* Booking visit questionnaire (appendix 7)
[†] This option was added 5 months after the study began

group' and then 'it's not necessary as I've no chance of being positive'. A moderate number felt that they would rather not know if they were positive and did not want to think about HIV during pregnancy. There was also some worry about the effects on insurance. However, very few women reported that they were worried about being HIV positive or that they were advised against testing (Table 16).

Did those who took the test regret doing so?

Of those who took the test and completed this questionnaire item ($n = 690$), only 17 (2.5%) reported that they regretted having taken the test. Ten women felt that it made them more worried, three had worries about confidentiality or prejudice, one said her partner had moaned about her taking the test, another that she felt pressurised into making a decision and another that there had been too much information given.

Is the HIV test any more or less anxiety-provoking or reassuring than any of the other antenatal tests?

The mean anxiety and reassurance levels for each antenatal test are shown in Table 17. The numbers reporting for the HIV, AFP and CF tests are lower because many women reported that they didn't have these tests. The AFP test had the highest anxiety rating. HIV testing was rated as less anxiety provoking than all other tests apart from the test for syphilis. Women were most reassured by the results of the scan. Getting the result of the HIV test was rated as less reassuring than all other tests apart from syphilis.

Taking the sub-sample of women ($n = 211$) who took all the tests including the HIV test, repeated measures analyses of variance showed a significant difference between the different tests in the extent of anxiety and reassurance (see Table 17).

This analysis is based on small numbers and should thus be regarded with caution.

Is the HIV test valued as highly as other antenatal tests?

As shown in Table 18, the HIV test was not valued as highly as the other tests. The scan was rated as the most important test, followed by tests for AFP, CF,

TABLE 16 Reasons for not taking the HIV test: description of sample

Reason	Number of women*
I would rather not know if I'm positive	132
I don't want to think about HIV when I'm pregnant	142
I was worried about effects on insurance or mortgage	119
I was advised not to by a midwife	12
I might be forced into a termination if positive	25
I am worried that I might be HIV positive	4
Family and friends put me off having the test	8
It's not necessary as I've no chance of being positive	578
I've been in a stable relationship for a long time	826
I have been tested elsewhere	181
My partner has been tested elsewhere	97
I'm not in a high-risk group	710
It was not offered to me	20

* Women who did not take the test were asked to select two reasons from the list; see appendix 7

TABLE 17 Mean level of anxiety and reassurance about specific antenatal tests at follow-up

Test (no. of women)*	Mean (SD) anxiety [†]	Mean (SD) reassurance [†]
Syphilis (677)	1.2 (0.47)	2.1 (1.1)
Rubella (758)	1.5 (0.75)	2.7 (1.0)
Scan (805)	2.2 (1.0)	3.6 (0.7)
AFP (670)	2.6 (1.0)	3.3 (0.9)
HIV (328)	1.4 (0.7)	2.6 (1.2)
CF (567)	2.0 (0.9)	3.0 (1.0)
Repeated measures analyses of variance ($n = 211$)	$F = 110.14$, $p < 0.001$	$F = 78.17$, $p < 0.001$

* Women who had the test were asked to answer questions concerning the results. See the Return visit questionnaire reproduced in appendix 8
[†] Each item in appendix 8 part 1 was scored separately on a scale 0–4

TABLE 18 Mode rating of importance of specific antenatal tests at follow-up

Test	Mode for entire sample	Mode for those who took HIV test
Scan	1 (= most important)	1 (= most important)
AFP	2	2
CF	3	3
Rubella	4	4
HIV	5 (= least important)	5 (= least important)
See Return visit questionnaire (appendix 8)		

rubella and finally HIV. Including only those who had taken the HIV test, the pattern was the same, indicating that even women who take the test do not value it more highly than other tests. Taking each intervention group and the control group separately, the pattern was also the same, indicating that different methods of offering the test do not affect the low value attached to HIV testing.

Are participants who took the HIV test satisfied with the way the result was given?

Of the small number of women who responded to the two questions relating to satisfaction with test result, 171 (59%) said they had received their result within a week, 50 (17%) said that they had not and 68 (24%) said they were unsure.

Most respondents (i.e. 242, 93%) were, however, satisfied with the way the result was given.

Summary and discussion

The majority of women were in favour of HIV testing being available and very few felt that it should be available on a 'request only' basis. From the reasons given for taking the test and from comments made relating to the best method of offering the test, it seems that there is strong support for the test becoming more routine.

The comparison of anxiety and reassurance about HIV testing with the other antenatal tests showed different results from previous research.¹⁴ Our data indicated that women found HIV testing one of the least anxiety provoking tests whereas the previous study¹⁴ found it to be one of the most worrying. It was also considered to be one of the least reassuring test results to receive in the present study, but one of the most reassuring test results in the previous study.¹⁴ This suggests that women in Edinburgh are less anxious about HIV than the sample in London and perhaps women who experience the test actually being offered (this study) may be less anxious than those who are asked to imagine how they would feel (the previous study¹⁴). However, this conclusion can only be made with caution, in view of the differences in sample sizes involved in the statistical comparison between means (i.e. $n = 76$ for the previous study and $n = 211$ for the present study). Moreover, in the present study, the women were asked to rate six antenatal tests as opposed to five in the previous study, and there were a couple of differences in the actual tests the women were required to rate. In our study CF and syphilis tests were added and blood pressure removed.

Chapter 10

Costs of the different methods of offering testing

The financial costs were calculated for a year in terms of cost of the HIV tests, cost of leaflet production, administration of result-giving, midwife training time and time taken for discussion of HIV testing. Costings are shown for the methods of offering the test to all women (Table 19) and for the 'request only' protocol, as in the control group (Table 20).

Since the different types of intervention resulted in the same uptake rate (35%), the only difference between the different interventions was the time taken for the midwife to discuss testing. An overall saving of £2600 would be made with the minimal discussion protocol compared with the comprehensive discussion protocol (Table 19).

Alternatively, a 'request only' procedure (control

group) with a 5.5% uptake, which is probably an overestimate considering the women in this trial were told individually that the test was available, would cost only £3321 (Table 20). Yet the low cost is not an advantage of this method if positive women go undetected. In a case of unknown serostatus, no medical intervention can take place and there is a one-in-five chance that the baby will become infected, resulting in very high possible medical costs.

The cost of an HIV test shown is the amount required by the laboratory when the sample is taken in the same tube as for another antenatal blood test (i.e. testing for syphilis or rubella). The cost would be slightly more if the sample was taken separately. There is a possibility that with bulk testing, the cost could be reduced.

TABLE 19 Financial costings for universal voluntary testing programmes

Item	Costs	Total
Cost of HIV test	1750 tests @ £7.00 per test	£12,250
Leaflets	5000 leaflets @ £25 per box of 100	£1250
Administration of results		
Midwife time	4 hours per week @ £9.75 per hour	£2028
Stationery	1750 first-class stamps @ £0.26 each	£455
	1750 envelopes	£75
	1750 photocopies of letter	£34
Midwife training		
Two afternoons' leave in lieu of attendance at training sessions	8 hours for 10 midwives @ £9.75 per hour	£780
Midwife time for pre-test discussion		
Comprehensive discussion protocol	5000 × 7.7 minutes @ £0.1625/minute	£6256
Minimal discussion protocol	5000 × 4.5 minutes @ £0.1625/minute	£3656
Total cost for comprehensive discussion programme for 1 year		£23,128
Total cost for minimal discussion programme for 1 year		£20,528
Saving made with minimal discussion programme for 1 year		£2600
All costs are based on an annual delivery rate of 5000 women and an HIV testing uptake rate of 35%		
Midwife costings are based on a basic F grade annual salary of £15,715 + employer's costs of 21%		
Discussion protocol timings are based on average time taken in the trial		

TABLE 20 Financial costings for 'request only' testing programme

Item	Costs	Total
Cost of HIV test	275 @ £7.00 per test	£1925
Leaflets	None	–
Administration of results		
Midwife time	0.5 hours per week @ £9.75 per hour	£254
Stationery	275 first-class stamps @ £0.26 each	£72
	275 envelopes	£12
	275 photocopies of letter	£5
Midwife training		
Two afternoons leave in lieu of attendance at training sessions	8 hours for 10 midwives @ £9.75/hour	£780
Midwife time for pre-test discussion	Discussion time 275 × 6.1 minutes @ £0.1625/minute	£273
Total cost of 'on request' programme for 1 year		£3321
<p><i>All costs are based on an annual delivery rate of 5000 women and an HIV-testing uptake rate of 5.5%</i></p> <p><i>Midwife costings are based on a basic F grade annual salary of £15,715 + employer's costs of 21%</i></p> <p><i>Discussion protocol timings are based on the average time taken in the trial for the control group, where the extent of discussion was at the midwife's discretion</i></p>		

Chapter 11

Midwives make a difference: the midwives' role in the uptake of testing

Introduction

Midwives are in a key position to offer antenatal HIV testing^{13,37} and they are already involved in offering all other blood tests, both routine (e.g. rubella) and non-routine (e.g. AFP). However, if midwives are to offer HIV testing they need to have the knowledge and confidence to do so. Some authors have suggested that lack of knowledge may lead to higher anxiety amongst midwives and there may also be legal implications of not giving up-to-date and unbiased information.⁸

The midwife may have a very important impact on whether a woman decides to be tested. In a London study of 448 pregnant women seen by 12 midwives, Meadows and colleagues³⁴ found that women's uptake of HIV ranged between 3% and 82% depending on the midwife offering the test. It was not possible for these authors to examine detailed characteristics of the midwives involved in offering testing, although the data suggested that ethnicity of the midwives may have had some effect on uptake. They speculated that other individual characteristics of the midwife may have been involved including age, number of years qualified, knowledge about HIV disease, attitudes to the antenatal test and differences in the counselling approach used.

In our trial, we found that an important predictor of uptake was the midwife seen (see chapter 7). We aimed to determine, in this part of the study, whether the different uptake rates could be explained by midwives' age and status and their knowledge and attitudes. However, more important perhaps than the midwives' own knowledge is the knowledge she conveys to the women and the manner in which this is done. Achieving a high uptake is undesirable if the women are not well informed and/or are made particularly anxious by the procedure. Therefore, this part of the study also aimed to determine the impact that each individual midwife had on the knowledge and anxiety of the women she saw.

Method

Study group

A group of ten midwives was involved in seeing most women attending the clinic for their first (booking) visit. The mean age of the midwives was 35 years 10 months (SD = 8 years 2 months; range = 29–57 years). The mean number of years qualified as a midwife was 9 years 11 months (SD = 10 years 1 month; range = 1–36 years). The midwives were all female, British and Caucasian.

Procedure

The midwives were given training before the trial began as detailed in chapter 2.

During the trial, uptake of HIV testing was assessed by asking each midwife to complete a checklist for every client seen, noting whether or not she took the test. She also noted her own personal code which allowed us to monitor the uptake rate for each midwife. The differences in numbers of women seen by individual midwives can be explained by midwives' sick leave as well as by natural differences in consultation time of the midwives.

In the last week of the trial the midwives were issued with a knowledge and attitudes questionnaire. All ten midwives completed this. Other details with regard to midwives' age and status was obtained directly from each midwife.

Measures

The midwives' questionnaire was devised with reference to other work which has investigated midwives and other health professionals' attitudes towards HIV.^{38–43}

A knowledge score was devised by adding the scores obtained for 15 statements which included transmission of HIV, testing, the window period and prevention of vertical transmission. Each statement had a five-point Likert-type response scale ranging from 'strongly disagree' to 'strongly agree'.

Confidence scores were determined by adding the scores from five items with Likert-type response

scales asking how confident the midwife felt about discussing sexual practices and drug habits, as well as how much knowledge, confidence and experience she thought she had in discussing HIV testing.

The impact the midwives had on the women was measured using the HIV knowledge and anxiety components of the booking questionnaire (see chapter 5 for details).

The data were analysed using SPSS for Windows. Chi-squared tests were used to compare proportions of women taking the test by midwife and to compare proportions of women with correct knowledge about AZT and breastfeeding by midwife. Spearman's rank correlations were used to examine the relationships between midwife variables (e.g. age, knowledge and individual uptake rates). One-way analysis of variance (*F* test) was used to compare the mean time taken for HIV discussion by midwife and the mean anxiety levels for the women by midwife.

Results

The midwives' impact on the women they saw was assessed by looking at uptake rates, midwives' knowledge and confidence, time taken for consultation and women's knowledge and anxiety after the consultation. This is shown in *Table 21*.

HIV test uptake rates

As reported in chapter 7, uptake rates varied significantly from 15% to 48% for the ten different midwives ($\chi^2 = 97.03$, $df = 9$, $p < 0.0001$).

Midwives' age and years qualified

There was a tendency for client's uptake to increase with midwives' age ($r_s = 0.32$, $p = 0.37$) and there was a stronger relationship between the number of years qualified as a midwife and clients' uptake ($r_s = 0.54$, $p = 0.10$ but these observations were not statistically significant).

Midwives' knowledge

Knowledge scores ranged from 61 to 74 (mean = 67.6, SD = 4.4, maximum possible score = 75). There was no relationship between clients' uptake and midwives' knowledge ($r_s = 0.15$, $p = 0.68$).

Midwives' confidence

Post-study confidence scores ranged from 11 to 18 (mean = 14.5, SD = 2.3, maximum possible score = 23). In general, uptake rate increased with midwives' confidence, although the relationship was weak and not significant ($r_s = 0.31$, $p = 0.38$).

Midwives' attitudes

Responses to the following questions highlighted differences between the midwives with high and low uptake rates:

TABLE 21 Midwives' uptake rates in ascending order, the number of women seen, midwives' confidence and knowledge, women's specific knowledge about HIV, women's anxiety, and time taken for HIV discussion for the ten individual midwives

Midwife	No. of women seen	Uptake rate (%)	Midwives' knowledge score (out of 75)	Midwives' confidence score (out of 23)	Women's knowledge (% correct)		Women's anxiety mean score	Average time (minutes) taken for:	
					AZT*	Breastfeeding†		Minimal discussion	Comprehensive discussion
A	353	15	59	15	27	41	11.2	6.47	7.07
B	134	16	64	14	46	49	10.9	2.79	5.59
C	316	17	63	14	32	38	10.9	2.78	6.24
D	312	22	62	11	20	40	11.0	3.62	6.76
E	170	24	72	17	31	44	11.1	4.80	8.49
F	492	28	72	12	40	56	11.1	4.53	9.85
G	263	30	66	13	29	44	11.1	3.89	8.11
H	188	32	67	14	34	50	11.1	3.65	7.54
I	361	33	62	17	18	31	10.9	5.28	5.44
J	138	48	62	18	51	63	10.5	5.96	8.54

* This refers to the item 'a pregnant woman who has HIV can reduce the chance of her baby becoming infected by taking zidovudine (AZT)' (see Booking questionnaire, appendix 7)
† This refers to the item 'a pregnant woman who has HIV can infect her baby through breastfeeding' (see Booking questionnaire, appendix 7)

'Are you in favour of HIV testing being offered routinely to pregnant women?'

Eight out of the ten midwives responded 'yes' and two responded 'unsure'. The two who responded 'unsure' were the two midwives with the lowest and the third lowest uptake rates.

'Do you think that pregnant women are sensible if they choose to take the HIV test? If so, why? If not, why not?'

Answers to this question varied: some midwives were not able to say 'yes' or 'no'.

I don't quite view uptake of the test as being sensible or not sensible ...

If they are making an informed choice, yes. But if they do not truly consider the implications of testing, then no.

Depends on personal decision.

Others said 'yes', but only on condition.

If in a high-risk group then definitely sensible to choose to take the test

Yes, as long as they have a full understanding

One midwife was unconditional in her support of all women being sensible in taking the test, whether or not they were at high risk of HIV infection.

Yes, I think women are sensible if they choose to take HIV testing as they are keen to know that they are not infected with the virus. If they were, they could plan their future by being better informed.

The midwife who made this final comment had the highest uptake rate.

'Should midwives aim at increasing the number of women tested?'

Five midwives responded 'no', four responded, 'unsure' and only one said 'yes'. The midwife who said 'yes' had the highest uptake rate.

'Do you think that HIV testing should continue in the clinic from now on?'

Six midwives responded 'yes' and four responded 'unsure'. Three of those who responded 'unsure' had low uptake rates: 15%, 17% and 22%.

Time taken for discussion about HIV testing

The mean time for discussion of HIV testing was calculated for each midwife for the two different types of discussion protocol used for the main trial: minimal and comprehensive. There was a significant difference between the midwives in the time taken to discuss testing both for the minimal ($F_{9,840} = 15.7, p < 0.001$) and the comprehensive protocols ($F_{9,928} = 13.4, p < 0.001$). However, the

correlations between time taken and clients' uptake of testing for the minimal ($r_s = 0.32, p = 0.36$) and comprehensive protocols ($r_s = 0.33, p = 0.35$) suggested that although the length of time taken increases with clients' uptake, the relationships are weak. Moreover it is not possible to determine whether length of time taken affected uptake or vice versa. It may be that midwives who had higher uptake rates had longer average discussion times because they had more to discuss with women who were taking the test.

Women's knowledge

There was a significant difference between the midwives in terms of their clients' specific knowledge, both about AZT ($\chi^2 = 93.8, df = 9, p < 0.0001$) and breastfeeding ($\chi^2 = 75.2, df = 9, p < 0.0001$). The clients of the midwife who had the highest uptake rate were significantly better informed about breastfeeding than clients who saw any of the other midwives and significantly better informed about AZT than those who saw most of the other midwives.

Women's anxiety (STAI)

There was no significant effect of midwife on women's anxiety overall. However, the women seen by the midwife with the highest uptake had the lowest mean anxiety and the women seen by the midwife with the lowest uptake had the highest mean anxiety.

Discussion

Meadows and colleagues³⁴ suggested that the difference in uptake rates could be explained by the midwives' counselling approach and their ethnicity. However, in our study, despite uniformity of counselling procedure and ethnicity, wide variations in uptake still occurred. Other factors were weakly but not significantly associated with HIV test uptake – the age of the midwife, number of years qualified, her confidence and time taken to discuss HIV.

Midwives' own knowledge about HIV was not associated with uptake of HIV testing. It is well documented that attitudes are more important than knowledge in determining behaviour.⁴⁴ Although greater knowledge can result in more positive attitudes, this is not always the case. Robbins and colleagues⁴⁵ investigated the relationship between knowledge, attitudes and degree of contact with AIDS and found that although military nurses had greater knowledge than psychology students or design students, their attitudes were not as positive.

Looking in greater depth at the midwives' attitudes in this study, it was found that the midwife with the highest uptake had strikingly different attitudes from the others. She was the only midwife who felt that the midwives should aim at 'increasing the number of women tested'. She also thought women who undertook testing for HIV were 'sensible' regardless of their risk status. In contrast, all the others expressed doubts about whether it was 'sensible' for all women to undertake testing especially if they did not perceive themselves to be at risk or they had not considered the matter carefully. Moreover, midwives with the lowest uptake were not positive about HIV testing being offered in the clinic. It was quite clear that a positive attitude towards testing – that is with no doubts that the test was beneficial for all pregnant women, that testing should be offered in the clinic and that it was the midwife's role to increase uptake – is the attitude which resulted in the highest uptake. Doubts about whether testing was beneficial for all women and whether testing should be promoted resulted in lower uptake rates, even in this situation where all midwives were required to offer the test.

We felt it was also important to analyse the impact of the midwife on the women she saw. The Department of Health guidelines¹⁷ require informed consent before testing for HIV is carried out and there is increasing awareness amongst midwives of the need to give clear, research-based information throughout pregnancy so that women can make informed choices.⁴⁶ The data show that the midwife with the highest knowledge did not impart that knowledge most effectively, suggesting that knowledge alone does not necessarily lead to effective communication. Sherr²⁵ has stated that communication may be ineffective for a number of reasons: time constraints, lack of training, lack of motivation, interpersonal problems and misunder-

standings. It would appear therefore that all those areas need to be addressed in order to increase effective communication, and that simply giving knowledge training is not enough.

High uptake is not appropriate if the women are made anxious by the procedure and/or are not well informed. This study was able to show clearly that the midwife who had the highest uptake rate did not raise anxiety levels and her clients were significantly better informed than those who saw other midwives.

The average length of time taken to discuss testing was only weakly related to uptake rate. This suggests that it is not the length of time taken which affects the woman's decision to take the test and supports the finding from the main trial that the minimal and comprehensive methods produced the same uptake rates. So it is clearly not a matter of **how much** you say, but **how** you say it.

One main strength of this study is also a shortcoming. The restricted number of midwives involved allowed a rigorous, uniform approach. However the small number meant there was limited statistical power to explore knowledge and confidence. The attitudes survey was qualitative and therefore limited in how well it can be related to subsequent behaviour. However, this study has highlighted factors that are likely to be important when considering how midwives can affect their clients' decision-making about HIV testing. These factors, especially attitudes, should now be considered in greater detail and with larger, predictive studies.

The fact that the midwives' attitudes towards the test has such an effect on uptake may be important, not only with regard to the offer of HIV testing but with regard to any screening test midwives offer.

Chapter 12

To test or not to test? A comparison of women who took the test with those who did not

Introduction

This study was carried out as part of the main RCT. The data have indicated that different methods of offering the test do not affect uptake (see chapter 7). In an attempt to explain uptake, we have examined demographic and situational variables. Some demographic factors were found to be associated with uptake in multivariate analyses: younger and unmarried women were more likely to take the test. Also, the midwife who offered the test was found to be an important predictor (see chapter 7). A detailed investigation of the midwives found that the midwife's knowledge was not related to her uptake rate; her attitudes and the knowledge she conveyed to the women were much more important (see chapter 11).

Following these investigations we wanted to further our understanding of the uptake of testing by examining the women's attitudes in more detail and how they may have affected their decision to take the test. People's attitudes and beliefs towards testing may be influenced by factors such as their marital status and their age, but it is their attitudes and beliefs that are the most readily changeable and which are the focus of most psychological research into the determinants of uptake of screening tests.

Social cognition models have been applied in many studies examining health-relevant decision-making including uptake of screening. The Health Belief Model^{47,48} is widely used and has been found useful in the prediction of screening uptake.⁴⁸ In the context of HIV testing this model would predict that an individual will be more likely to take an HIV test if they perceive HIV as a personal threat, if they believe the benefits of taking the test outweigh the costs and if they receive a cue to action to trigger this decision-making process.⁴⁸ This cue to action can be internal, such as symptoms, or external, such as a reminder phone call or letter. In the context of deciding whether to take an HIV test when offered, as in this study, the cue-to-action component is not relevant, although it would be if the woman had to request an HIV test.

Meadows and colleagues²⁴ found that intention to take an HIV test was predicted by perceived benefit of the test to the woman herself, her partner and the midwife and perceived risk of HIV infection. The present study attempted to explain actual uptake behaviour, not just intention.

Other factors that may help to explain uptake of testing may be attitude towards the test during pregnancy and knowledge of the benefits of HIV testing. Attitude is defined as an important predictor of intention in another important social cognition model, the theory of planned behaviour.⁴⁹ Knowledge is not postulated as a direct predictor of behaviour by the social cognition models, but as one of the factors which is likely to influence beliefs.

This study attempted to explain uptake by investigating the women's individual responses. The main research question was: how do women who accept the offer of HIV testing differ from those who do not in terms of their knowledge, health beliefs and attitudes? A secondary aim was to determine to what extent these cognitive variables would be predictive of uptake in comparison with the demographic factors and the midwife effect.

Methods

Sample

The present sample included those who were offered the HIV test by a midwife: the control group (n = 994) from the main trial were not included as they were not offered the test and we wished to investigate decision-making about testing in the context of being offered a test directly. Of the remaining 2030 women, the resulting study sample of 1817 were those who completed the patient questionnaire immediately following the consultation (90% response rate).

Design

In a retrospective survey design, two groups were compared: those who had taken the HIV test ('testers') and those who had decided against testing ('non-testers') on the basis of their specific

knowledge about breastfeeding and AZT, their attitude towards the availability of the HIV test in pregnancy, perceived benefits for the baby, the mother, the midwife and research, and perceived risk of HIV.

Measures

The aspects of the questionnaire that we used to compare testers and non-testers were as follows: specific knowledge about breastfeeding and AZT; attitude towards the availability of the HIV test in pregnancy; perceived benefits for the baby, the mother, the midwife and research; perceived risk of HIV. (See chapter 5 for details on measures.)

Statistical analyses

All variables were transformed into dichotomous variables:

- responses were coded as either correct or incorrect/don't know for specific knowledge items
- responses were coded as either 'in favour' or 'not in favour'/'unsure' for attitude towards the availability of testing in pregnancy
- the response scales for the perceived benefits items were dichotomised (due to severe negative skewness) as perceiving great benefit (i.e. the top point of the four-point scale) or not perceiving great benefit (codes 1 to 3)
- the response scale for perceived risk was also dichotomised due to severe negative skewness as perceiving some to high risk (points 1 to 4,

where 1 = very likely to be infected) or perceiving no risk (point 5 = very unlikely to be infected).

Chi-squared tests were thus used to compare testers with non-testers in terms of percentage correct for the knowledge items, percentage in favour of testing, percentage perceiving great benefits and percentage perceiving some to high personal risk of HIV. Due to the number of chi-squared tests being performed ($n = 8$), the Bonferroni correction was used to control for inflated alpha. Logistic regression analysis was used to determine the multivariate predictors of uptake and the odds ratios and 95% confidence intervals for each significant predictor.

Results

Uptake

There were 642 testers (35%) and 1175 non-testers (65%).

Health beliefs and attitudes (univariate analyses)

Table 22 presents the results of chi-squared tests comparing testers and non-testers. Testers were significantly more likely to have correct knowledge about breastfeeding, had more positive attitudes towards the availability of testing in pregnancy and perceived greater benefits of the test for the baby, the midwife, the mother and for research. Although testers had more knowledge about AZT

TABLE 22 Differences between testers and non-testers in knowledge, beliefs and attitudes about HIV testing

Variable	Testers (%)	Non-testers (%)	Chi-squared test*
Knowledge of breastfeeding [†] (% correct)	55.9	48.9	$\chi^2 = 8.0$, $df = 1$, $p = 0.005$
Knowledge of AZT [‡] (% correct)	41.9	36.5	$\chi^2 = 5.1$, $df = 1$, $p = 0.02$ NS
Attitude towards availability of test (% in favour)	97.2	85.6	$\chi^2 = 59.6$, $df = 1$, $p < 0.0001$
Perceived benefits (% perceiving great benefit)			
For baby	81.7	67.6	$\chi^2 = 40.7$, $df = 1$, $p < 0.0001$
For midwife	64.0	55.2	$\chi^2 = 12.9$, $df = 1$, $p = 0.0003$
For mother	68.2	54.3	$\chi^2 = 32.2$, $df = 1$, $p < 0.0001$
For research	65.4	53.3	$\chi^2 = 24.2$, $df = 1$, $p < 0.0001$
Perceived risk of HIV (% perceiving some to high risk)	15.3	10.9	$\chi^2 = 7.2$, $df = 1$, $p = 0.007$ NS

* The Bonferroni corrected significance level for eight tests is 0.006 (i.e. 0.05/8)
[†] This refers to the item 'a pregnant woman who has HIV can infect her baby through breastfeeding' (see Booking questionnaire, appendix 7)
[‡] This refers to the item 'a pregnant woman who has HIV can reduce the chance of her baby becoming infected by taking zidovudine (AZT)' (see Booking questionnaire, appendix 7)

TABLE 23 Logistic regression analyses (forward conditional method): statistically significant predictors of uptake of HIV testing

Significant variables	Wald significance	df	Odds ratio*	95% confidence interval
Attitude towards testing	$p < 0.0001$	1	5.7	3.1–10.3
Midwife	$p < 0.0001$	10	–	–
Marital status	$p < 0.0001$	1	0.5	0.4–0.6
Perceived benefits for baby	$p < 0.0001$	1	1.8	1.4–2.4
Perceived benefits for research	$p = 0.002$	1	1.4	1.1–1.8
Perceived risk	$p = 0.031$	1	1.4	1.0–1.9
Knowledge about breastfeeding	$p = 0.047$	1	1.2	1.0–1.6

* Odds ratios are calculated on the basis of a positive attitude towards testing, for being married as opposed to unmarried, perceiving great benefits for the baby and for research, perceiving oneself to be at some to high risk and having correct knowledge about breastfeeding. A single odds ratio cannot be calculated for the overall effect of all the midwives

than non-testers and had higher perceived risk, these differences were not significant following Bonferroni correction.

Cognitions, demographic and situational variables (multivariate analyses)

We entered all the cognitive variables into logistic regression analyses along with the demographic and situational variables we had previously shown to be independently predictive of uptake (i.e. marital status, age, midwife seen and whether or not the woman had had a previous HIV test; see chapter 7). As shown in *Table 23*, significant independent predictors of uptake were, in order of importance:

- being in favour of the availability of testing
- the midwife seen
- marital status
- perceived benefits for the baby
- perceived benefits for research
- perceived risk of HIV
- knowledge that breastfeeding can transmit HIV.

Three of the cognitive variables were not independent predictors of uptake: knowledge of AZT; perceived benefits for the mother; perceived benefits for the midwife. Age and having had a previous test were no longer independent predictors of uptake in this analysis.

Discussion

The main advantage of this study over previous studies in this area is the large sample size and the use of actual behaviour (i.e. uptake of testing) as

the outcome measure, rather than intention to test. The data illustrate that cognitive processes are associated with uptake of HIV testing in antenatal care and may be more important than some demographic and situational factors. This provides important additional insight which could be used to encourage an increase in testing rates.

Variables drawn from the health-belief model were useful in explaining differences between testers and non-testers. In the multivariate analyses, perceived benefits relating to the baby and to research were significantly associated with uptake, but those relating to the mother or to the midwife were not. Perhaps the benefits to the woman's own health in terms of the recent achievements of combination therapy for reducing viral load should also be stressed when testing is being offered.

In the theory of planned behaviour, attitude towards performing the behaviour is an important factor in determining behaviour, mediated by the intention to perform that behaviour. Although the measure of attitude used in this study (i.e. 'Are you in favour of the HIV test being available for pregnant women?') could be described as less personally oriented than the attitude component of the model, it was still the strongest predictor of uptake: those who were in favour were almost six times more likely to take the test than those who were not.

Although knowledge was associated with uptake, it was less important than women's beliefs and attitudes. This is consistent with our finding that midwives' knowledge was not related to women's uptake and that their attitudes seemed to be more

important (see chapter 11). It also relates to the views of Marteau and Johnston³⁵ who highlighted the importance of the health professionals' attitudes, not their knowledge, when trying to explain patients' behaviour. These findings challenge the common viewpoint that providing information is enough to affect people's health-related behaviour and provides more evidence to support the psychological models' assertions that beliefs and attitudes, rather than knowledge, are the main pre-determinants of behaviour.

Implications for practice

It is acknowledged that the variables found to be associated with uptake in this study cannot be assumed to reflect causal relationships because the variables were measured **after** the women had decided for or against testing. Ideally, prospective studies should be carried out to determine to what extent these beliefs **cause** uptake as opposed to being a **result** of uptake. However, unfortunately, in the current study the measures could not be gathered before the offer of the test. This was because this study formed part of the RCT, the aim of which was to compare different approaches to offering testing on subsequent uptake and acceptability. We were concerned that asking

women to complete a questionnaire on health-beliefs before making the test decision might influence their decision beyond the effect of the standardised information given.

Nevertheless, the study highlights important cognitive differences between testers and non-testers which should not be ignored in future interventions when an increase in uptake of testing is desired. The data suggest that information given to women should focus on benefits of testing for the baby, particularly the possibility of reducing transmission, if the test is positive, by not breast-feeding. Although less fundamental, information could also attempt to increase women's perceived risk, particularly for those who are in stable relationships and may feel they are at no risk. However, increasing knowledge by providing information is only the first step. Changing women's beliefs and attitudes towards testing is necessary to affect uptake. The attitude of the midwife offering the test is important, in order to convey the offer of the test in a positive light. Making the test more routine, which is seen as a good idea by many women, may be another way of increasing positive attitudes towards the test, thereby increasing uptake. (See annex, page 81.)

Chapter 13

What do pregnant women think about the HIV test? A qualitative study

Introduction

The main disadvantages of offering HIV testing in pregnancy are the financial cost of offering testing and the negative psychological effect of a positive result. However, it has also been suggested that the offer of testing alone may increase anxiety and reduce satisfaction with the antenatal consultation for all women, not only those at high risk of infection.^{13,50}

We considered it important to determine what women thought and felt about issues of HIV testing in some detail, and so we undertook a qualitative study to complement the quantitative data. This involved interviewing a small number of women to determine what they thought of the information provided, the offer of HIV testing and the issues HIV testing raised for them and their partners. As Berg⁵¹ notes, 'qualitative procedures provide a means of accessing unquantifiable facts about the actual people researchers observe'.

This is not the first study of women's opinions with regard to HIV testing. Beevor and Catalan⁵² investigated the views of HIV-positive and HIV-negative women with regard to HIV testing, Sherr and colleagues¹⁴ looked at women's intentions to take testing and their opinions of testing, and Stevens and colleagues⁵⁰ assessed the acceptability of HIV testing amongst pregnant women in an inner London clinic. These studies produced mainly quantitative data and individual participants were either at high risk of HIV infection⁵¹ or were asked about their opinions and intentions about testing but were not actually offered the test.^{14,50} The present study differs from these other studies in that it uses qualitative methodology to investigate the opinions of women in the context of a specific offer of HIV testing.

Method

Sample selection

Potential interviewees were selected from the antenatal clinic by choosing each third woman on the clinic timetable sheets for 6 consecutive half-day clinics in August 1996, then five consecutive clinics in September and again in October. The final

participants were selected from three consecutive clinics in January 1997. The selected women were approached after their consultation with the midwife and after they had completed the questionnaire for the RCT. In total 60 women were approached and 29 agreed to be interviewed. Twenty-three women did not agree to be interviewed. The majority of those who did not agree were working full-time ($n = 20$) or had more than one child at home to look after ($n = 2$) and did not have the free time for a half-hour interview. Only one woman said 'I don't fancy it [the interview]'. A further five women agreed, then cancelled before the interview took place. In one case, the interviewer cancelled due to illness and two women were not suitable for other reasons (one lived too far away for the interviewer to visit and another was not at home when the interviewer visited).

The women interviewed and those who refused to be interviewed were compared with regard to age, parity, marital status, employment and deprivation (Table 24). Deprivation scores were derived from postcodes. Scores 1–3 signify higher affluence than

TABLE 24 A comparison of the current sample with those who refused the interview and the total sample from the main trial on demographic variables: means and proportions

	Total sample (n = 3023)	Accepted interview (n = 29)	Refused interview (n = 23)
Mean age (SD)	29.5 (5.4) years	31.9 (4.5) years	29.1 (6.1) years
Married	71%	62%	52%
Employed	65%	74%	60%
Housewife	28%	26%	35%
Parity			
Primiparous	49%	38%	52%
Multiparous	51%	62%	48%
Deprivation score in range 1–3*	55%	56%	42%

* Deprivation scores range from 1 to 7. The sample was split into two groups, one with scores 1–3 (affluent) and the other with scores 4–7 (deprived)

scores 4–7.³² Although those who were interviewed were more likely to have children already (multiparous) and therefore to be available for a home interview, there were no significant differences in any of these variables between women who agreed to be interviewed and those who did not. Those who agreed to be interviewed were also compared with the RCT sample to determine whether the group willing to participate in the interview was representative of the population of pregnant women in the area. The two groups were found to be very similar in terms of key demographic attributes (*Table 2A*).

The interview

The interview (*Box 1*) questions were mostly open-ended, allowing women to talk freely about any aspects of their visit to the antenatal clinic, but also enabling the interviewer to prompt the women with regard to the offer of HIV testing. There were some further questions which the interviewer asked only of those women who had taken the HIV test ($n = 8$), which related to how they felt about waiting for the result and how the result had actually been given.

Analyses

The transcripts were analysed to identify current themes with reference to the method described by Glaser and Strauss⁵³ as ‘grounded theory’. In this design, external categories are not imposed on the data, but emerging and recurrent themes are identified, and views according with or opposing these are juxtaposed to determine the extent to which given themes were present or absent in the accounts of other respondents. The transcripts were analysed separately by another member of the research team to ensure the validity of the identification of themes. The main themes identified were:

1. attitudes to availability of test
2. perception of risk
3. benefits of testing
4. attitudes to communication about testing
5. anxieties
6. opinions on getting test results.

In this study the results were not quantified. The small sample size and the qualitative design did not make this appropriate. The analyses sought only to identify the issues important to a group of women and to illustrate their opinions in some detail.

Results

Overall women appeared positive about their antenatal consultation and no one mentioned HIV testing until asked specifically about it. This

BOX 1 Interview schedule
Can you tell me what were the particularly good aspects (if any) about your visit to the antenatal clinic?
Can you tell me what were the particularly bad aspects (if any) about your visit to the antenatal clinic?
How did you feel about the HIV test being available to you at your booking visit?
How did your partner feel about the HIV test being available for you at your booking visit?
What did you think of the leaflet that was sent to you containing information about HIV testing?
How do you feel about the way your midwife discussed the subject of HIV testing with you?
Was there anything about the way that you were offered the test which you were not happy about?
Did you and your partner discuss taking the HIV test before coming to the clinic?
Would you have preferred for your GP or your consultant or someone else to offer you the HIV test?
Did you take the test?
If yes, ask the following...
What do you think of the way your test result was given to you?
How often did you think about the HIV test and your result in the week following testing?
Did you discuss the HIV test with anyone after you had been tested?
If so, with whom did you discuss it?
If you had been found to be HIV positive do you think you would have considered terminating your pregnancy?
What do you think is the best way to offer the HIV test to pregnant women?
What do you think is the best way to give the result to women who have chosen to take the HIV test?
What did you think of the questionnaire the researcher asked you to fill in?
Is there any aspect at all about the clinic that you would like to see changed?

suggests that the offer of HIV testing did not affect these women in a negative way.

Availability of testing

When the subject of testing was raised, all women were happy for HIV testing to be available.

I think it is an excellent idea because ... there are so many, especially heterosexuals, that think ‘oh well it will never affect me and I will never have it’ but the fact is you could ...

However, this positive attitude towards availability did not mean that they thought they should accept testing for themselves. Most women who did not take the test just did not perceive themselves to be at risk (see next section). However, there was some evidence of concern about the possible implications of a positive test.

It is quite scary because you think it could come back and I could find out I am HIV positive and I don't know how I would have coped with that, but I do think it is a good idea that it is available.

The women offered opinions about how testing should be made available. The idea of routine testing occurred frequently.

If it was a compulsory thing I would have been quite happy to have it done. It is difficult to ask for it.

... perhaps people would be happier if they thought there was no stigma attached to having it done so if it could be offered in that way ... I think it should be done with everybody and you get a chance of knowing if you want.

One issue about availability of testing that caused women concern related to how insurance companies would view their having a test. Information in the leaflet and from the midwife regarding the statement by the Association of Insurers that insurance companies only wish to know of HIV-positive status, not testing status, did not seem to instil confidence.

... there is this thing when people had tests a few years ago and your insurance company found out about it ... the fact that you have had a test, let alone what the result was. Even though there is nothing wrong with me, it would be in the back of my mind.

Perception of risk

Those women who referred to the issue of risk of HIV infection tended to perceive themselves as being at low risk.

... I said to the midwife at the time that I didn't mind taking one [the HIV test] but I am not in a high-risk category. I have my ex-husband and the person I am with now over the last 7 or 8 years so I wasn't classed as high risk so there was no need to take it.

Some women specifically wanted the midwife to tell them whether they were in a 'risk category' and what their level of risk was. Midwives were seen as having expertise in risk assessment.

I would be prepared to sit down and give someone my precise history if at the end they would be able to say: 'well I think you are a low risk, medium or high', but it is really hard to judge yourself.

Benefits of testing

Much was said about the benefits of offering testing during the booking visit but that was usually with reference to benefits for the baby; no one spoke of perceived benefits to themselves of testing.

... if you find out in advance to know that things can be done for the baby once it is born, it doesn't actually mean the death sentence ...

Even where information had been provided by leaflet and pre-test counselling, women did not always remember what the benefits were.

I wasn't clear what the benefits to the baby were. If I was HIV, what are the benefits of knowing well in advance of the baby being born? What preparation can be made or what steps can be taken to help the situation?

However, if they did know about the benefits, they tended to think more positively about HIV testing.

I didn't realise there was anything you could do to help the baby whilst in the womb – I wasn't aware of that and if that was the case I certainly wouldn't have a problem.

... She [the midwife] gave it from quite a theoretical perspective: why some people choose to take the test and why not and some of the benefits of having the test during pregnancy. That was the only reason that I decided to, because there was something that could be done for the baby if it was picked up at that stage.

Communication about HIV testing

Most women felt the leaflets were well written and easily understood. There seemed to be an opinion that the leaflets were interesting, but not particularly relevant on a personal level.

It [the 'HIV-specific' leaflet] was clear and well explained. I read it, but in my mind put it aside. I am sure it is probably not right, but I saw myself as this not being directly relevant to me so I understood it, but set it aside afterwards.

The women felt that there should not be too much information which may discourage them from reading the entire leaflet, but also thought that the leaflet was good in helping to raise the issue.

I think if there is a lot more information written down people won't make the effort to read it ... too much information ... they will reject it, so maybe, the leaflet is good in actually raising the issue and maybe desensitising the issue ...

Thus, sending only written information may mean that many women who do not read material unless they consider it to be directly relevant will remain un-informed. There needs to be a verbal component so that the benefits are re-emphasised.

Although most women said the leaflets were fine, interesting and informative, one woman felt insulted initially, just because she had been sent it (the 'HIV-specific' leaflet).

When we got the letter through, that was all in it and I felt a bit insulted at that time. It wasn't until I thought about it, about people who take drugs or whatever else they do and end up the way they do end up, and some end up that way through no fault of their own, then I thought well yes it is a good thing and they can't differentiate between one person and another. They are not to know what kind of lifestyle everybody has so I suppose they just have to cover the whole spectrum and everybody will take it in their own way.

Although the midwives were given standard protocols they all approached the pre-test discussion in their own way and this is reflected in the comments made by the women. Some women felt the midwife introduced the subject naturally and dealt with it well. They did not appear to feel pressurised and felt able to ask their midwife questions.

She was great. She gave me a lot of information – all relevant, no embroidery of the facts. She discussed everything and if I felt unsure about something I didn't feel that I couldn't ask her to go over or recap. In fact I did do that a couple of times and she was great.

However in some instances there appeared to be confusion about the nature of the test and the way in which the midwives offered it. This may have been partly because in the minimal discussion protocol the information given about the HIV test was brief: midwives were trained to go into detail only if the woman asked questions or indicated little understanding of the nature of the test.

I felt she could have been more helpful. I didn't really know exactly whether it was a routine thing or whether only some people were being asked about it and she wasn't forthcoming with information and I couldn't make up my mind whether I should take it or not. I didn't think I required to take the test and I was thinking, 'well, was there some information I could have which would influence my choice?'. But obviously she didn't think it was up to her to say whether I should have it or whether I shouldn't have it.

Perhaps this provides some insight into consultations with health professionals in general and patients' reluctance to raise questions, even when they are not sure of the test being offered.

Anxieties

The major anxiety expressed was that of having a baby with an abnormality such as spina bifida

or Down's syndrome. For some women everything else was insignificant, so it did not matter what other tests they were offered during pregnancy.

Actually it is a funny thing, but even although HIV is a really serious issue and everyone who has had sexual intercourse with anyone should really think about it, the thing I would be most worried about would be the foetus and how it was developing. That overtakes everything, it really does. For some reason, you want to know if the child is spina bifida or I want to know if it is Down's syndrome and that takes up most of your thinking time during the day. ... HIV seems to take a sort of backseat.

However women who accepted testing (n = 8) did express some anxiety whilst waiting for the HIV result and were glad that they did not have to wait longer than a week.

I am not expecting it to come back with anything other than a negative test, but since Tuesday I have thought, 'well I hope the test is all right and why did I take the test', so I suppose it didn't really sink in until actually I had left the clinic what I had actually done and although you think I am not at risk, I have nursed pre-AIDS patients and so of course the last couple of nights I thought, I hope I have followed the protocol and I hope this test isn't positive. Although I'm not expecting it to be, there is a certain amount of anxiety as well. I suppose it is like any test that you have, you worry about the results.

Getting test results

The optimal way of getting their HIV test result was the area which gave rise to most discussion. Although the women had different ideas about the best way of getting HIV results there were common themes running through the comments.

In general, women thought it was acceptable to receive a negative result through the post and all eight women who took the test were satisfied with receiving their result in this manner.

I am quite happy to have it through the post as long as it's negative.

They wished to be told results, not left to assume that 'no news is good news'.

... I remember with the CF test you just didn't hear and that meant you were negative and I found that a bit unsatisfactory because you do think, 'well is it missing in the post?'

A few women (n = 6) wished to be given an HIV result, positive or negative, in person, and a couple of women felt that getting a result for the HIV test should not be any different from the other antenatal tests

I would rather that they said, 'you come back in 2 weeks' time and you will get the results of all your tests'... and it is all done as one package.

I think it should be just one of the normal tests and I don't think we should differentiate and make this one so much more different from trying to detect a child with any other disease or identify the risk of a child having any other disease and being able to treat it.

All women thought that a positive result should be given in person and acknowledged that there was no 'good' way of breaking bad news.

I don't know if there is a good way. I think I would like to be told by someone. Not written down ...

Discussion

Informed choice with regard to care during pregnancy is the gold standard.⁴⁵ To ascertain the acceptability of HIV testing, women's opinions were sought through an in-depth interview. They were asked specifically how they felt about the offer of HIV testing as an antenatal test. Two out of the 29 women interviewed said they did not appreciate being offered it, but all the other women thought the offer was acceptable. The uptake of testing, however, was only 28% (eight out of 29) indicating that, although women feel that the test is acceptable, they do not necessarily feel it is a test they want to take. The quantitative data also supports this finding – 88% of women who completed a questionnaire thought the offer of HIV testing was a good idea (see chapter 9) but the uptake rate was only 35%. Comparing this with previous studies, a clear pattern emerges. In a study of women attending for antenatal care at a hospital in London, Stevens and colleagues⁵⁰ found that although 82% of women thought HIV testing should be offered, only 48% felt it was a test they would have. Barbour and colleagues⁵³ found that attenders at a family planning clinic in Scotland were happy for other groups (e.g. intravenous drug users) to be tested on a compulsory basis. This attitude suggests that most women perceive themselves to be at low risk and therefore believe that testing is not something they need. However, they are positive about the availability of testing for those whom they perceive to be at high risk.

Women were not asked specifically about benefits to them or their baby and it was interesting that no one mentioned benefits for themselves of knowing their HIV status. This is perhaps surprising in view of the publicity surrounding the achievements of combination therapy. The benefits to the woman

of early diagnosis should therefore be stressed when testing is being offered. More women felt that there were benefits for the baby of knowing their serostatus but they did not mention specific benefits. A psychological model of health behaviour, the Health Belief Model,⁴⁶ proposes that one of the precedents of taking health action is perceived benefit. Thus if women were told more about specific benefits for both themselves and their baby they might be more likely to accept HIV testing.

This study has given insight into the issues that women think are important in pregnancy and those which provoked anxiety. Contrary to some health professionals' beliefs,³⁸ HIV testing did not appear to cause women much anxiety – they were much more concerned about having a baby free of abnormality. Stevens and colleagues⁵⁰ found that women attending an antenatal clinic in inner London thought that the offer of HIV testing would cause them more anxiety than other antenatal tests. However, in this study, where women were actually offered testing, this was not the case.

However, the women who opted for HIV testing did express some anxiety while waiting for the result or just before opening the envelope containing the result. Marteau⁵⁵ states that most antenatal testing procedures and results are associated with negative emotion and it would appear from our study that HIV is no exception. However, the women did not remain worried after they had received their result. Moreover, women expressed relief and reassurance from a negative result.

Most women in our study were at low risk and expected a negative result, and were content to receive this by post. This corresponds with findings of Smith and colleagues⁹ in Dundee who found that only 4% of women wished to be told a negative result in person. A small number of women felt that both positive and negative results should be given in person, but this can be time-consuming and expensive although some health professionals still consider it to be the best way of giving results, even when negative.³⁷ Some women we interviewed thought that having to come back for a result that was negative would cause unnecessary anxiety. It may be time to consider how results are given to women accepting universal antenatal HIV testing. As more women receive their antenatal care in the community, it may be possible to give the HIV result along with the other blood test results at the next routine clinic appointment, and to inform women that they would be recalled sooner

if any blood tests were abnormal. The logistics of calling a large number of women back to the antenatal clinic solely for their HIV result would prove too much for clinics already stretched to their limit. This is an area that will need further review if uptake of testing increases.

Some women felt that it would be easier if the decision to be tested were taken out of their hands and testing could be done routinely. There was also a common view that the test should be treated in the same way as any other antenatal test. These opinions reflect the findings of the main trial, in

which the most frequent reason given for being tested was 'it's a good idea to have it as a routine test' (see chapter 9). Studies carried out in Sweden and France have shown a high acceptance of HIV testing as a routine antenatal test and low anxiety levels amongst women being tested.^{15,56} The information we have gathered about pregnant women's attitudes suggests that a move towards the HIV test becoming the recommended norm in antenatal care, although not compulsory, is likely to be acceptable, would probably increase uptake rates and should therefore be assessed. (See annex, page 81.)

Chapter 14

Overall summary of answers to research questions and conclusion

The answers to the research questions of this study (see chapter 1) can be summarised as follows.

- 1a. Offering the HIV test as opposed to the test being available on request (control group) resulted in a significantly higher uptake (35% versus 6%). However the four combinations of methods of offering the test did not result in different uptake rates. In other words, uptake was not affected by type of leaflet or style of pre-test discussion.
- 1b. Neither offering the test in comparison with the control group nor the method of offering the test affected anxiety (either at booking or follow-up), satisfaction with the consultation, general knowledge about HIV, knowledge about other antenatal tests or attitudes towards pregnancy. Specific knowledge about HIV transmission from mother to baby was affected by method of offering the test, such that those who received the 'HIV-specific' leaflet and the comprehensive discussion were the most likely to have this knowledge. This provides evidence that offering specific information within the written information and discussion with the midwife, preferably both, can increase women's knowledge and therefore their competence to make an informed choice about testing. The perceived benefit of testing was also affected by method of offering the test, such that those who received the comprehensive discussion following either of the leaflets perceived greater benefits for the baby.
2. Of the 760 women tested during the trial, one woman was newly identified as HIV positive. One woman was already known to be HIV positive and a further three HIV positives were detected by the unlinked, anonymised Guthrie testing, but were not tested in the clinic during the period of the trial. Two of these three unknown positives were in the control group.
3. The midwife had an important effect on uptake. The uptake rates associated with the individual midwives ($n = 10$) ranged from 15% to 48% and the midwife seen was the second most significant predictor of uptake after being offered the test. There was also an effect of midwife on women's specific knowledge.
 4. The group of women seen by the midwife with the highest uptake had the greatest specific knowledge. There was no significant effect of midwife on women's anxiety.
 4. Some demographic factors were predictive of uptake: being unmarried and younger were multivariate predictors; being socially deprived was a univariate predictor, as was being unemployed. These predictors may be a surrogate marker of HIV risk (e.g. drug use or having several sexual partners). However, parity and area risk (in terms of number of HIV cases in postcode area) were not related to uptake. Age was the only demographic variable that modified the effect of the different ways of offering testing such that older women 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.
 5. Perceived personal risk of HIV infection was associated with uptake such that those who perceived some to high risk of infection were more likely to take the test than those who perceived no risk.
 6. The majority (88%) of pregnant women who responded to the questionnaire were in favour of the HIV test being made available to all pregnant women; 3% were not in favour and 9% were unsure.
 7. The method of offering testing that gained most approval from the women was sending an information leaflet then a short, pre-test discussion with the midwife (up to 5 minutes).
 8. 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 long stable relationship or not being in a 'high-risk group' seemed to be the main reason underlying the responses given for not taking the test.
 9. The HIV test was found to be less anxiety provoking when compared with most of the other antenatal tests (i.e. AFP, CF carrier test, rubella and ultrasound scan).
 10. The HIV test was not valued as highly as any of the other antenatal tests measured (i.e. AFP, ultrasound scan, CF carrier test and rubella).

11. Most (93%) of the respondents to the follow-up questionnaire who had taken the HIV test were satisfied with the way the result was given.
12. The costs of the different programmes for a universal offer of testing are very similar because the only difference is the time taken by the midwives to discuss testing. Calculated on the basis of a unit with an annual delivery rate of 5000 women and an HIV testing uptake rate of 35%, the total annual costs would be approximately £23,128 and £20,528 for a comprehensive and a minimal discussion programme respectively. A 'request only' policy would be much cheaper at approximately £3321 per annum.
13. An in-depth study of the midwives indicated that their knowledge, although generally good, was not associated with their clients' uptake rates. Their age and number of years qualified, their confidence and the time taken to discuss HIV testing were all weakly, but not significantly, associated with their uptake rates. 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.
14. A qualitative study of pregnant women's opinions about being offered HIV testing revealed that few women were made anxious about being offered the HIV test. They were much more concerned about having a healthy baby. Because of this concern, women who had retained information about the benefits of testing for the baby's health seemed to think the test was useful. Although the majority felt that the test should be available during pregnancy, there was a common view that the test was irrelevant for them as an individual. Those who took the test, however, expressed anxiety whilst waiting for the test result. There was no clear consensus about how the test result should be given. Although most women seemed content to receive a negative result through the post, others preferred that it should be given in person.

Conclusion

The antenatal booking visit is a sensitive time when a lot of information is being exchanged and it is thus extremely important that the introduction of a new screening test will not adversely affect the experience. This, added to the controversy surrounding HIV testing, has led to particular concern among health professionals about the introduction

of HIV testing into antenatal care. The present data suggest that this apprehension is unfounded. Women were willing to discuss their attitudes to HIV testing and were positive about the availability of testing. Moreover, the universal offer of testing did not appear to be intrusive to the booking visit or to cause anxiety, and was not inappropriately time consuming.

In London, where there is a higher prevalence of HIV infection in pregnancy, testing policies are failing to detect the majority of HIV-positive women before they give birth.⁷ During our study, only one out of four unknown positives was detected. There is therefore an urgent need to define the factors that will increase uptake and detection rates. The results of this study show that requiring the midwives to offer the test and documenting that offer results in a 35% uptake rate which is certainly more effective than a policy of making the test available on request. However, 35% is not a high uptake rate, particularly in comparison with the rates of over 90% achieved in many European countries.¹⁰ So, 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 ('opt-in' approach), is not an effective way of achieving high uptake and detection rates.

However, women found the test acceptable, no matter how it was presented, and the most frequent reason given for taking the test was 'it's a good idea to have as a routine test'. In the light of this evidence, and in support of the recent assertion that 'the time has come to bring HIV antibody testing alongside other diagnostic screening tests',³⁷ we propose that the uptake and acceptability of an 'opt-out' approach to testing should be assessed. Such an approach would involve providing concise, but specific, information and discussion and then carrying out the test, unless the woman chooses not to be tested. (See annex, page 81.)

Limitations of the study

The study was conducted in one hospital in Edinburgh and thus it cannot be assumed that the results will generalise to other areas. In London, a high proportion of HIV infection is found in women of African origin, whereas in Edinburgh there are very few women from ethnic minorities. It may be that women from different ethnic backgrounds respond differently to the offer of an HIV test during pregnancy. Also, this study was carried out in one hospital with a small number of midwives dedicated to antenatal care. Although this setting was ideal for running a RCT with close monitoring of the midwives, some of the findings

may be limited to this type of setting. In areas where community midwives undertake the majority of bookings or in hospitals where there is a higher turnover of midwifery staff it may be more difficult, for example, to set up effective training programmes and to ensure that midwives

are actually offering the test to all women. The effect of the midwives on uptake of testing shown in this study is unlikely to be diminished in different settings. If anything, the difference between midwives who are not working closely together are likely to be exaggerated.

Chapter 15

Implications of this research

Suggestions for the offer of testing

1. 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.
2. If midwives are asked to keep a record of each offer made, this may increase uptake rates.
3. Both 'HIV specific' and 'all blood tests' leaflets showed advantages. As a compromise we recommend that a leaflet containing information about 'all blood tests', but including some more information about HIV and specifying clearly the benefits of testing during pregnancy, should be assessed in practice.
4. A minimal approach to discussion costs less in terms of midwives' time, but we suggest that a minimal approach should contain specific information on the benefits of testing as our data show that this will increase women's knowledge.

Suggestions for midwives' training

1. Midwives should be given information about HIV and HIV testing. However, it is likely that increasing their positive attitudes towards testing will have a greater effect on uptake than their personal knowledge about HIV.
2. A midwife's ability to convey knowledge about the test to her clients is likely to result in a better response to the offer of testing in terms of informed uptake. Thus communication skills rather than information-giving should be highlighted in training. Perhaps role-playing sessions with other midwives and feedback discussions, after the midwives have had some experience in offering the test would help to increase these skills. An on-going support

network between the midwives is important to address any problems that only arise with experience, such as time constraints or having to deal with a hostile response.

3. Written protocols with points to remember to say in the discussion are also important for increasing the ability to convey information and should be made available in each consulting room.
4. It is important to bolster the midwives' confidence by reminding them that they are well experienced in offering screening tests and that, in general, they do not require any special skills to offer the HIV test. In the event of a positive result or when clients have difficult questions or are very anxious, midwives should always have easy access to an experienced HIV counsellor for advice and support.
5. We propose that it should remain the woman's choice to reject the test and that midwives should be trained to accept this decision without reproach.

Recommendations for future research

1. Midwives play an important role in affecting uptake, and research should focus on differences between midwives which may affect uptake rates. Their attitudes appear to be important and thus future research should consider ways of determining how to alter midwives' attitudes.
2. We propose that in areas where an increase in uptake of testing is desired, a routine approach to testing where 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. (See annex, page 81.)



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Appendix I

Letter sent to potential participants

Dear

A study investigating different approaches to HIV testing in pregnancy: acceptability, costs and benefits.

You are probably aware that HIV infection continues to be a problem in Edinburgh. Fortunately, amongst pregnant women in this area, the level of infection seems to be falling.

We want to find the best method of making the HIV test available to pregnant women so that they are fully informed about the options available to them, but without making people unduly anxious. For women who test positive, there are benefits to themselves and their babies of knowing this in advance. However, we do need to find out how best to offer this service. This is what our study is all about.

Over the next few months we're going to be trying different approaches to the provision of information about HIV to women attending the ante-natal clinic. You may find yourself in one of the groups getting a leaflet about HIV and/or other tests and your midwife may talk to you about this subject. You'll almost certainly be asked to complete a brief questionnaire about HIV testing and other tests offered in the clinic. We want to know how you feel about the service. Your responses will help affect how the service is offered to pregnant women in the UK in the future.

Whatever happens in the study, you will always be able to choose whether or not you want an HIV test. If you are not offered the test, but want to be HIV tested, please just ask your midwife.

If you decide not to participate in the study by not completing a questionnaire, this will not affect the quality or the nature of the care you receive in the clinic.

If you have any questions about this study, please do not hesitate to ask the researcher in the ante-natal clinic – she will be happy to talk to you about it. We'd like to thank you in advance for the help you may give us in this important study.

Yours sincerely

Wendy Simpson
Project Leader

Appendix 2

Clinic poster

The HIV Test is available

part of caring for you and your baby

Please ask if you want a test

We want to offer a service which
suits you

You may be asked to fill in a
questionnaire

We want to know:

- How you feel about HIV testing during pregnancy
- How much information you want

If you are offered the test you can say
yes or no

You have the choice

Appendix 3

‘HIV-specific’ leaflet

What is HIV?

- HIV stands for **H**uman **I**mmunodeficiency **V**irus and is the virus which causes AIDS.
- HIV attacks the body's immune system and breaks down its ability to fight disease and infections.
- Most people with HIV are healthy for a long time, often for 10 years (on average) after infection. Many people carry on with their normal lives.
- When a person with HIV develops serious illnesses due to their weakened immune system, they are said to have AIDS. This stands for **A**cquired **I**mmune **D**eficiency **S**yndrome.
- There are drugs, therapies and support which can help people with AIDS. However there is no cure at present.

How is HIV spread?

HIV can be passed on in the following ways:

- Having sexual intercourse with someone who is already infected.
- Sharing drug injecting equipment with someone who is already infected.
- Receiving a blood transfusion of infected blood. Since 1985 all blood in Britain has been tested, but this is not the case in all countries.
- Receiving a donation of sperm from an infected man. However all donors in recognised fertility clinics will have been tested.
- From an infected mother to her baby, although the possibility of this can be reduced.

People who have HIV can pass on the virus in the above ways even when they look and feel healthy.

What will happen at the clinic?

The midwife will offer you an HIV test at your booking visit.

If you choose to take the test, the sample of blood which we take to test for syphilis will also be tested for HIV. We will not give you another needle prick.

If you choose to take the test, we will contact you by letter one week after testing with your result.

You may not wish to take the test at this time. You may want more time to talk it through with your partner or a friend before you make your decision. There are other places where you can go for testing if you wish (see below).

*If you choose **not** to take the test, we will not test your blood sample for HIV*

You may now have enough information to begin to decide whether to take the HIV test or not. If you have any questions, please ask the midwife at your booking visit.

Other places where you can have the HIV test

If you wish they can offer you the result on the same day as you're tested.

HIV Counselling Clinic City Hospital For appointments and advice: Telephone: 0131 536 6484	Genito-Urinary Medicine Clinic Royal Infirmary of Edinburgh For appointment or advice: Telephone 0131 536 2104
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Screening tests in pregnancy
Part of caring for you and your baby

HIV Testing at the Booking Clinic

Simpson Memorial Maternity Pavilion
The Royal Infirmary of Edinburgh
NHS Trust

To test or not to test ...

... that is your choice.

This leaflet explains why the HIV test is available at the clinic as part of your care during pregnancy. It gives you general information about HIV and HIV testing.

Take time to read this information and note any questions you have.

When you attend the clinic you can discuss these with the midwife before you make your decision.

Why do we offer the HIV test to pregnant women?

When you register for ante-natal care we offer you several medical tests. These are to check that all is well for you and your baby.

These tests can also alert you, your midwife and your doctor to any problems that may require special monitoring or care.

HIV testing is one of these medical tests. It is being offered to pregnant women in areas of Britain where HIV infection is more common, as in Edinburgh.

In order to become pregnant you will have had unprotected sexual intercourse. This is one of the ways in which HIV can be transmitted.

Most pregnant women have a negative HIV test result.

If the result is positive, we can offer special care to the woman to help prevent the baby being infected.

What is the HIV test?

The HIV test involves taking a blood sample. When someone is infected with HIV they produce antibodies to the virus. The HIV test looks for these antibodies in the blood. The result of the HIV test is either **positive** or **negative**.

What does a positive result mean?

A positive result means that the person is infected with HIV. However it does not mean that they have AIDS. It can take about 10 years (on average) to develop AIDS from time of infection.

What does a negative result mean?

A negative result usually means that the person is not infected with HIV. However, it can take 3 months or more for the antibodies to HIV to appear. This means that it is possible to have been infected, but for the test to be negative. So, we advise further testing if someone thinks they may have been infected within the past 3 months.

Why can taking the test be a good idea?

Some women can find it helpful to know if they are infected or not.

If the result is positive the woman will be able to make choices about her pregnancy and health:

- She can have special treatment (AZT) which has been shown to cut down the number of babies becoming infected by two thirds.
- She can choose whether or not to breastfeed. HIV may be passed on by breastfeeding.
- She can choose to have a caesarean section. This may also reduce the chance of the baby becoming infected.
- She can get treatment for herself.
- She can make decisions about carrying on with the pregnancy. She may wish to terminate the pregnancy. However, many HIV positive women have their babies and are happy about doing so.
- She can have safe sex using condoms and plan for the future. There are support groups for HIV positive women.

A negative result can be very reassuring for people who think they may have been at risk.

Why can taking the test be a bad idea?

- Pregnancy can be very stressful. A woman can often feel anxious, tearful or sick. Waiting for the result of an HIV test can be very distressing. The possibility of a positive result may be too much for the woman to cope with. We would encourage people who want to take the HIV test to plan how they would cope and whom they would turn to if their result was positive.
- Unfortunately there is still much fear and prejudice about people who are HIV positive. Many people have had problems with housing, employment and personal relationships.

What about insurance?

Taking the HIV test would **not** prevent you from getting life insurance if the result is negative. The Association of British Insurers has recommended that its members no longer ask whether the applicant has had an HIV test or counselling. They should only ask whether the applicant has had a positive HIV test result.

People with a positive HIV test result are unlikely to get life insurance or a mortgage. However, their positive result will not affect any life insurance policies they already have.

Your ante-natal care

Whether or not you choose to take the HIV test, we will not change the care and attention you receive during your pregnancy.

If your test result were positive, we would not act differently towards you. However, we would offer you extra care and help.

Appendix 4

‘All blood tests’ leaflet

Screening tests in pregnancy
Part of caring for you and your baby

3. Syphilis

This sexually transmitted disease is now rare. We test for this because untreated syphilis can have very serious effects on the baby. Treatment of the mothers with penicillin will prevent these serious effects. There is therefore real gain for the occasional pregnancy affected.

4. Rubella (German Measles)

An infection with the rubella virus in the first 3 months of pregnancy causes abnormalities in most babies. Most women are now immune to rubella. Over 95% of our female population are immunised at school. If you have satisfactory levels of immunity, your baby is not at risk.

The purpose of the test is to confirm immunity. It will also identify women who are not immune so that they can have immunisation after delivery. Some women who have been immunised previously have low levels of immunity on testing. Such women are offered a "booster" immunisation after delivery.

Follow-up for Routine Blood Tests

If there is something you should know as a result of any of the tests, the midwives from the clinic will inform your GP. He/she will pass the information on to you and give you time to ask any questions you may have.

Other places where you can have the HIV test

HIV Counselling Clinic
City Hospital
For appointments and advice:
Telephone: 0131 5366484

Genito-Urinary Medicine Clinic
Royal Infirmary of Edinburgh
For appointment or advice:
Telephone 0131 5362104

If you wish they can offer you the result on the same day as you're tested.

Blood Testing at the Booking Clinic

Simpson Memorial Maternity Pavilion
The Royal Infirmary of Edinburgh
NHS Trust

*If you have any questions about any tests
please ask the midwife
you see at the booking clinic*

As part of your care during pregnancy we offer you several blood tests. This leaflet explains the tests that are, or can be done on the sample of blood we will take from you at your booking visit.

Take time to read this information and note any questions you have. When you attend the clinic you can discuss these with the midwife.

Tests available, but not routine

At present, we don't routinely screen everyone for either Hepatitis B or HIV. However, the midwife will talk to you about the HIV test. We can do these tests easily if you want them, without giving you another needle prick.

1. Hepatitis B

This is a virus which particularly attacks the liver. It is much more common in some parts of the world (especially in Far East, Africa and parts of Asia), where the virus is usually spread from mother to child. It is also spread sexually or through injection drug use. We believe that few mothers in Edinburgh are carriers but we have no accurate information. Without a test, there is no way the mother herself will know whether she is infected.

Hepatitis B is relevant for pregnant women. If the mother is a carrier, her baby will probably become infected during delivery. A quarter of these children go on to have fatal liver disease. However, we can prevent most babies being infected by immunising them very soon after birth.

2. HIV

This virus can be passed through blood, semen or vaginal fluid. It is not easily passed from one person to another. The virus, which causes AIDS, gradually destroys the immune system and makes you unable to fight disease. It can take about 10 years (on average) to develop AIDS from time of infection.

The virus can be passed from a mother to her baby during pregnancy or at delivery. If we know that a mother is infected we can give her special care. This will help to make it less likely that her baby becomes infected.

If the blood result is positive this means that the person is infected with HIV. It does not mean that they have AIDS.

A negative result usually means that the person is not infected by the HIV virus. However, it can take 3 months or more for the antibodies to HIV to appear. So, we advise further testing if the person thinks they may have been at risk of infection within the past 3 months.

A negative HIV test does not affect past or future life insurance claims.

If you choose to take the test, we will contact you by letter one week after testing with your result.

You may not wish to take the test at this time. You may want more time to talk it through with your partner or a friend before you make your decision. There are other places where you can go for testing if you wish (see back page).

*If you choose **not** to take these tests,
we will not test the sample of blood taken
for Hepatitis B or HIV*

Blood tests which are routine for all pregnant women at booking

1. Full Blood Count

This test sorts out and measures the cells in blood. The main purpose is to detect anaemia, a reduced number of red cells carrying oxygen through the blood system. However, sometimes the test may suggest other conditions such as shortage of iron or some types of hereditary abnormality.

2. Blood Group

This test tells us three different things about your blood:

- 1: whether you belong to group A, B, O or AB.
- 2: whether you belong to the Rhesus positive or Rhesus negative group. One in six women are Rhesus negative.
- 3: Whether there are any unexpected blood group antibodies in your blood as a result of a previous transfusion or pregnancy.

If you are Rhesus negative we will give you an injection called "anti-D" if you bleed during your pregnancy or if any invasive treatments are carried out, e.g. amniocentesis. After delivery of your baby we may want to repeat this injection. This is all explained in more detail in a booklet we will send you.

If you are Rhesus positive you will not hear from us.

Appendix 5

Midwives' HIV counselling protocol: minimal

1. Do you have any questions about the leaflet you were sent which gave information about HIV and HIV testing
 YES → Give leaflet to read again and answer questions [**GO TO 2**]
 ↓ NO
2. Do you want the test?
 NO → **STOP**
 ↓ YES
3. Do you understand what a positive result and a negative result would mean?
 NO → Explain positive and negative result [**GO TO 4**]
 ↓ YES
4. Explain procedure for taking test and giving results – both positive and negative
5. Fill in consent form
6. Take test

Appendix 6

Midwives' HIV counselling protocol: comprehensive

Introduce counselling

Have you read the leaflet you were sent along with your appointment?

(If not, give leaflet they were sent – see label.)

First of all I want to make it clear why we're offering the HIV test to you

If a pregnant woman has the HIV virus, the baby can become infected with HIV ...

- during pregnancy, labour and delivery
- as a result of breastfeeding.

If we know that a woman is HIV positive (by doing an HIV test), steps can be taken to reduce the risk of passing the virus from mother to baby.

HIV – what it actually is and how it is spread

HIV is a virus which causes AIDS.

It attacks the immune system and breaks down its ability to fight disease and infection.

It can be spread by:

- unprotected sex
- sharing needles when injecting drugs
- a mother to her baby during pregnancy and at delivery.

Between 1990 and 1995 the rate of infection in Edinburgh in pregnant women has been about 1 in 660.

The HIV test

It is a blood test which detects antibodies to the virus in your blood.

A positive result would mean that you were infected by the virus.

It would not tell you:

- if you have AIDS now or not
- how long before you develop AIDS
- when infection took place
- how infectious you are
- whether or not you will infect your baby.

A negative result means you have not developed antibodies against the virus.

This is most likely to mean that you do not have the HIV virus.

If you have been involved in risk behaviour in the last 3 months it may be that you are in the WINDOW PERIOD and have not yet developed antibodies to the HIV virus.

In this situation, it would be good for you to be tested in 3 months time.

The benefits of testing

- Relief to know – especially if negative.
- If you were to test positive:
- we can offer AZT in pregnancy and to the baby postnatally to reduce the risk of the baby being infected
 - you can plan your labour to reduce risk of the baby being infected
 - we can offer specialised help for the future
 - we can give relevant health education advice and support
 - it can allow you to make choices about carrying on with your pregnancy.

The disadvantages of testing

If you were to test positive

- there is no known cure for the disease
- treatments do not always help
- we do not know how long you would stay healthy

- there is still a lot of fear and prejudice.
Even if negative
- it can be stressful waiting for the result.

Insurance

If you apply for life insurance or a mortgage, the insurance company should not ask you if you have had an HIV test.

They should only ask if you have tested HIV positive.

Any questions?

Do you wish to be tested for HIV?

If the answer is **NO** then **STOP HERE**

If the answer is **YES** continue ...

Do you have any particular concerns which have made you decide to take the test at this time?

This should allow the woman to ask any questions about risk factors that she may be concerned about.

At this stage it is important to plan the possibility of your result being positive

- If we receive a positive result from the lab we would contact you to ask you to return for further testing – this may not mean that you are HIV positive – there may be a mistake.
- If you come for further testing you will get a same day result here at the clinic.

- You should think about who you would bring with you for support.
- You should think about who you would tell if the result were positive.
- You should think about how your partner and family would react – have you discussed testing with them?

If you were positive there is plenty of community support available, for example:

- GP
- Consultant Obstetrician
- City Hospital HIV Counsellors
- Body Positive – self-help groups and individual support
- Women HIV and AIDS Network – information service and pressure group for women's issues
- SOLAS – resource and information centre including café, arts projects, alternative therapies, etc.

What the test involves:

- no extra blood required
- same sample used as is used for syphilis
- the result within a week telling you are negative or asking you to come back for a second test.

Review

- Importance of testing in pregnancy.
- Advantages and disadvantages of testing.
- How the results would be given.
- The importance of remembering that being asked to be retested is not synonymous with being positive.
- The choice is yours.

Do you wish the test for HIV?

Appendix 7

Booking visit questionnaire

University of Edinburgh
Department of Obstetrics and Gynaecology

Booking Visit Questionnaire

Date:						
Consultant:						

NHS Executive

PART 1

Here are some questions which will help us to find out how good we are at explaining about tests. We do not expect you to know all the answers but please try.

1. First of all we want to know which of the following tests you had done at the ante-natal clinic.

Please tick one box for each line

- a scan yes no don't know
- rubella (German measles) yes no don't know
- cystic fibrosis carrier test yes no don't know
- AFP (or 'spina bifida') test yes no don't know
- HIV test yes no don't know
- amniocentesis yes no don't know
- Chorionic villus sampling (CVS) yes no don't know
- blood group yes no don't know
- hepatitis B yes no don't know
- syphilis yes no don't know
- toxoplasmosis yes no don't know

Please answer the following questions by ticking one box for each question

2. When you give a urine sample at the clinic, what is it routinely tested for?

- protein twins
- how old the baby is don't know

3. Amniocentesis is used to test for...

- diabetes pregnancy
- Down's syndrome don't know

4. What is the main use of ultrasound or scans early in pregnancy?

- to see what sex baby is to test for blood disorders
- to check age and growth of baby don't know

5. If a routine spina bifida test gave a result that suggested an above average risk, what would be likely to happen next?

- baby would be given immediate treatment
- termination of pregnancy would be offered
- more tests would be offered
- don't know

6. When is blood taken for the spina bifida test?

- 16-18 weeks in pregnancy 34-36 weeks in pregnancy
- when the baby is born don't know

7. When you give a mouthwash sample at the clinic what is it tested for?

- diabetes mouth infections
- cystic fibrosis carrier status don't know

8. If you and your partner have a positive cystic fibrosis carrier test, what is the chance of your baby having cystic fibrosis?

- 1 in 8 chance 1 in 4 chance
- 1 in 2 chance don't know

PART 2

Here are some questions about HIV, AIDS and the HIV test.

Do you agree or disagree with the following statements about HIV and AIDS?

Please tick one box for each question.

1. If someone gets a positive HIV test result, it means that they have AIDS.
 agree disagree unsure
2. HIV is a virus which causes AIDS.
 agree disagree unsure
3. A pregnant woman who has HIV can reduce the chance of her baby becoming infected by taking Zidovudine (AZT).
 agree disagree unsure
4. A pregnant woman who has HIV can infect her baby through breastfeeding.
 agree disagree unsure
5. A person can be infected with HIV and look well.
 agree disagree unsure
6. How can you become infected with HIV?
 - a. By kissing someone who is infected with HIV?
 yes no unsure
 - b. By having unprotected sexual intercourse with someone who is infected with HIV?
 yes no unsure
 - c. By giving a blood donation at a blood donor centre?
 yes no unsure

6. (cont.) How can you become infected with HIV?

- d. By a mosquito bite?
 yes no unsure
- e. By sharing needles for injecting drugs with someone who is infected with HIV?
 yes no unsure
- f. By being in a swimming pool with someone who is infected with HIV?
 yes no unsure
7. Do you feel you know as much about HIV and AIDS as you want to know?
 yes no unsure
8. How likely do you think it is that you are infected with HIV?
Please circle a number between 1 and 5, e.g. ④

1	2	3	4	5
very likely				very unlikely
9. Are you in favour of an HIV test being made available to all pregnant women?
 yes no unsure
10. If yes, what do you think is the best way of offering the HIV test to pregnant women?
Please tick one box only
 send information leaflet, then ask woman if she wants the test or not at the clinic
 send information leaflet, then short pre-test discussion with the midwife (up to 5 minutes)
 send information leaflet, then long pre-test discussion with the midwife (up to 15 minutes)
 do the test routinely like the test for rubella, without discussing it
 leave it up to the woman to ask the midwife if she wants a test
 don't know

PART 3

We are interested to know how satisfied you were with the standard of service in the ante-natal clinic.

Please tick one box for each question.

1. **The length of time waiting to see the midwife was ...**
 poor satisfactory good very good excellent
2. **The length of time you spent with the midwife was ...**
 poor satisfactory good very good excellent
3. **How easy it was to ask the midwife questions was ...**
 poor satisfactory good very good excellent
4. **How well the midwife answered your questions was ...**
 poor satisfactory good very good excellent
5. **The relevance of the information you received from the midwife was ...**
 poor satisfactory good very good excellent
6. **Overall, how would you rate your session with the midwife?**
 poor satisfactory good very good excellent
7. **If you saw a doctor, how would you rate your session with the doctor?**
 poor satisfactory good very good excellent

8. **Please let us know if there was any specific thing about your booking visit that you were not happy about.**

11. **How much benefit do you think the HIV test is ...**

Please circle a number between 1 and 5, e.g. ④

- a. **for the baby?** 1 2 3 4 5
 no benefit some benefit great benefit
- b. **for research?** 1 2 3 4 5
 no benefit some benefit great benefit
- c. **for the mother?** 1 2 3 4 5
 no benefit some benefit great benefit
- d. **for the midwives?** 1 2 3 4 5
 no benefit some benefit great benefit

PART 4

Below is a list of words which women may use to describe the way they feel about being pregnant and how they feel towards their baby.

Read each word, then circle the number to the right of the word that best describes the way you feel right now, for example, ②:

1. **How do you feel now about being pregnant?**

a. fulfilled?	not at all 1	2	3	4	very much 5
b. stressed?	not at all 1	2	3	4	very much 5
c. pleased?	not at all 1	2	3	4	very much 5
d. optimistic?	not at all 1	2	3	4	very much 5
e. worried?	not at all 1	2	3	4	very much 5
f. uncertain?	not at all 1	2	3	4	very much 5
g. depressed?	not at all 1	2	3	4	very much 5

2. **How do you feel now about the baby?**

a. uncertain?	not at all 1	2	3	4	very much 5
b. confident?	not at all 1	2	3	4	very much 5
c. attached?	not at all 1	2	3	4	very much 5

2. How do you feel now about the baby? (cont.)

- | | | | | | |
|----------------------|-----------------|---|---|---|----------------|
| d. loving? | not at all
1 | 2 | 3 | 4 | very much
5 |
| e. maternal? | not at all
1 | 2 | 3 | 4 | very much
5 |
| f. concerned? | not at all
1 | 2 | 3 | 4 | very much
5 |
| g. reassured? | not at all
1 | 2 | 3 | 4 | very much
5 |

Please make sure that you have answered **all** the questions.

A number of statements which people have used to describe themselves are given below. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer that seems to describe your present feelings best.

Read each statement and then circle the most appropriate number to the right of the statement to indicate how you feel right now, for example, ②:

- | | | | | |
|--------------------------|-----------------|--------------|-----------------|----------------|
| a. I feel calm | not at all
1 | somehow
2 | moderately
3 | very much
4 |
| b. I am tense | not at all
1 | somehow
2 | moderately
3 | very much
4 |
| c. I feel upset | not at all
1 | somehow
2 | moderately
3 | very much
4 |
| d. I am relaxed | not at all
1 | somehow
2 | moderately
3 | very much
4 |
| e. I feel content | not at all
1 | somehow
2 | moderately
3 | very much
4 |
| f. I am worried | not at all
1 | somehow
2 | moderately
3 | very much
4 |

Again, please make sure that you have answered **all** the questions.

PART 5

1. a. Did you take the HIV test?
 yes → if yes, please go to question 2
 no → if no, please go to question 5
 don't know → please go to questions 1b.+ c.
 it was not offered to me → please go to questions 1b.+ c.

- b. Were you aware that you could ask for the test if you wanted it? yes no
- c. Would you have taken the test if it had been offered to you? yes no **STOP HERE**

2. Following is a list of reasons for taking an HIV test that people sometimes give.
 Why did you decide to take the HIV test?
 Please tick two boxes only to show your two most important reasons for taking the test.
 - I was concerned about risks to the baby
 - I was concerned about my own health
 - I am/have been at risk of infection
 - I was persuaded by family and/or friends
 - my doctor thought it was a good idea
 - a midwife advised me to
 - to help research
 - because it was offered
 - it's a good idea to have it as a routine test

You may have other reasons for deciding to take the test which are not listed above. If so, please write them here.

3. What kind of result do you expect?
 positive negative unsure

4. Do you have any regrets about taking the test?
 yes no
 If yes, why? _____

STOP HERE
 Thank you very much for your time. Your answers are very important for helping us improve the service and care in the clinic.

5. Following is a list of reasons for not taking the HIV test that people sometimes give.
 Why did you decide not to take the test?

Please tick two boxes only to show your two most important reasons for not taking the test.

- I would rather not know if I'm positive
- I don't want to think about HIV when I'm pregnant
- I was worried about effects on insurance or mortgage
- I was advised not to by a midwife
- I might be forced into a termination if positive
- I am worried that I might be HIV positive
- family and friends put me off having the test
- it's not necessary as I've no chance of being positive
- I've been in a stable relationship for a long time
- I have been tested elsewhere
- my partner has been tested elsewhere
- I'm not in a high risk group
- it was not offered to me

You may have other reasons for deciding not to take the test which are not listed above. If so, please write them here.

Thank you very much for your time. Your answers are very important for helping us improve the service and care in the clinic.

Appendix 8

Return visit questionnaire

University of Edinburgh
Department of Obstetrics and Gynaecology

Return Visit Questionnaire

Date:					
Consultant:					

NHS Executive

PART 1

The following questions are about the antenatal tests which were routine at your booking visit.

Please tick one box for each question.

- 1. a. Were you worried while you were waiting for the result of your syphilis test?**
 No Yes, a little Yes, moderately Yes, very much Don't remember
- b. Did you feel reassured by having had the syphilis test?**
 No Yes, a little Yes, moderately Yes, very much Don't remember
- 2. a. Were you worried while you were waiting for the result of the blood test to check your level of immunity to Rubella (German measles)?**
 No Yes, a little Yes, moderately Yes, very much Don't remember
- b. Did you feel reassured by having had the Rubella test?**
 No Yes, a little Yes, moderately Yes, very much Don't remember
- 3. a. Were you worried while you were waiting to see your ultrasound scan?**
 No Yes, a little Yes, moderately Yes, very much Don't remember
- b. Did you feel reassured by having had the ultrasound scan?**
 No Yes, a little Yes, moderately Yes, very much Don't remember

The following questions concern the results of other tests which you may or may not have had.

- 4. a. Were you worried while you were waiting for the result of the AFP test (to predict the risk of Down's syndrome and Spina Bifida)?**
 No Yes, a little Yes, moderately Yes, very much I didn't have this test
- b. Did you feel reassured by having had the AFP test?**
 No Yes, a little Yes, moderately Yes, very much I didn't have this test
- 5. a. Were you worried while you were waiting for the result of the HIV test?**
 No Yes, a little Yes, moderately Yes, very much I didn't have this test
- b. Did you feel reassured when you received the result of the HIV test?**
 No Yes, a little Yes, moderately Yes, very much I didn't have this test
- 6. a. Were you worried while you waited for the result of the cystic fibrosis carrier test (mouthwash sample)?**
 No Yes, a little Yes, moderately Yes, very much I didn't have this test
- b. Did you feel reassured by having had the cystic fibrosis carrier test?**
 No Yes, a little Yes, moderately Yes, very much I didn't have this test

7. We are interested to know how important you think each of the antenatal tests is. Please rate, from 1-5, each of the following tests in order of importance to you:

- 1 = most important for you
- 2 = 2nd most important for you
- 3 = 3rd most important for you
- 4 = 4th most important for you
- 5 = least important for you

PART 2

Below is a list of words which women may use to describe the way they feel about being pregnant and how they feel towards their baby.

Read each word, then circle the number to the right of the word that best describes the way you feel right now, for example, ②:

1. How do you feel **now** about being pregnant?
 - a. fulfilled? not at all 1 2 3 4 very much 5
 - b. stressed? not at all 1 2 3 4 very much 5
 - c. pleased? not at all 1 2 3 4 very much 5
 - d. optimistic? not at all 1 2 3 4 very much 5
 - e. worried? not at all 1 2 3 4 very much 5
 - f. uncertain? 1 not at all 2 3 4 5 very much
 - g. depressed? not at all 1 2 3 4 very much 5
2. How do you feel **now** about the baby?
 - a. uncertain? 1 not at all 2 3 4 5 very much
 - b. confident? 1 not at all 2 3 4 5 very much
- 2.(cont.) How do you feel **now** about the baby?
 - c. attached? 1 not at all 2 3 4 5 very much
 - d. loving? not at all 1 2 3 4 very much 5 very much

- a. ultrasound scan? _____
- b. AFP test (blood test for spina bifida)? _____
- c. cystic fibrosis carrier test (mouthwash)? _____
- d. HIV test (blood test)? _____
- e. rubella test (blood test for German measles)? _____

Part 3

At your booking visit, you were offered the choice to take an HIV test or not. If you chose to take the test please answer the following questions.

1. Did you receive your HIV test result within a week?
 Yes No Unsure
2. Were you completely satisfied with the way your HIV test result was given to you?
 Yes No
 If not, please explain how you would have wanted to get your test result.
-

Thank you very much for your time. Your answers are very important for helping us improve the service and care in the clinic.

- e. maternal? 1 2 3 4 5
 not at all 1 2 3 4 5 very much
- f. concerned? 1 2 3 4 5
 not at all 2 3 4 5 very much
- g. reassured? 1 2 3 4 5
 not at all 2 3 4 5 very much

A number of statements which people have used to describe themselves are given below. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer that seems to describe your present feelings best.

Read each statement and then circle the most appropriate number to the right of the statement to indicate how you feel right now, for example, (2) :

3. a. I feel calm not at all 1 somewhat 2 moderately 3 very much 4
- b. I am tense not at all 1 somewhat 2 moderately 3 very much 4
- c. I feel upset not at all 1 somewhat 2 moderately 3 very much 4
- d. I am relaxed not at all 1 somewhat 2 moderately 3 very much 4
- e. I feel content not at all 1 somewhat 2 moderately 3 very much 4
- f. I am worried not at all 1 somewhat 2 moderately 3 very much 4

Appendix 9

HIV testing project: midwife checklist

Midwife Code	_____	
AN Number	_____	
Time started	_____	e.g. 10.42, 14.55
Time finished	_____	
HIV test taken	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Consent form signed	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Partner present	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Previous HIV test	Yes <input type="checkbox"/>	No <input type="checkbox"/>
IVDU present or past	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Partner or previous partner IVDU	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Nationality if English not first language	_____	
Comments		

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

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Annex

Antenatal HIV testing – assessment of a routine voluntary approach

Executive summary

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 the same 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 (SD = 1 minute 48 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.

Introduction

The benefits of testing pregnant women for HIV are increasingly assured, particularly in terms of measures that can reduce vertical transmission,^{1,2} but also because of the effectiveness of early treatment for the woman herself. However, uptake of antenatal HIV testing in the UK remains disturbingly low.³⁻⁵ This has been the focus of a national debate, though with reference mainly to inner London, where most pregnant women with HIV infection are living.³⁻⁹

The RCT described earlier investigated different methods of offering the test, compared with a control group. All methods involved giving the woman information and required her to make an active choice to be tested ('opt-in'). Before that study we, the midwives, and the patient representative groups we had consulted had several concerns: that the introduction of this screening test at such a sensitive time would adversely, if only slightly, affect many women's relationships with the midwife and obstetrician; that the additional information would reduce absorption of other health messages; that the link with past sexual behaviour might also colour the experience for many; or that a few women might be particularly upset by the offer. In fact, there were many reassuring features about the findings in the RCT. The midwives did not have a problem carrying it out, and women were willing to discuss their attitudes to HIV testing and were positive about the availability of testing. Moreover, the universal offer of testing did not seem to be intrusive to the booking visit or to cause anxiety, and it was not inappropriately time-consuming.

However, only 35% of women asked for a test, one of the two HIV-infected women in the intervention groups was not detected, and it is probable that this approach is not very effective in terms of case finding.

In addition, in a separate qualitative study, several women expressed the view that it would be easier if the HIV test was a routine test. In other words, it could be difficult for women to select themselves for testing ('opt-in') as they may feel this is indicative of risk behaviour. Instead, with the same written and verbal information available, the test could be done along with other blood tests at the time of booking, unless the woman didn't want it done. We therefore planned a study to assess this 'routine voluntary' model of offering testing, along the lines that 'the time has come to bring HIV antibody testing alongside other diagnostic screening tests'.⁹ Concise but specific information was

given, as before, and discussion was provided as necessary. However, the test was done automatically unless the woman chose not to be tested.

We have described the model as 'routine voluntary' because of concerns which have been expressed about the use of the term 'opt-out' (see discussion, page 90). The essential features of this approach are that it is based on the same requirements for information, choice and consent as the 'opt-in' model, but with a change in emphasis so that the test is done routinely unless the woman declines.

Methods

A submission to the Reproductive Ethics Committee was approved. Preliminary discussions were carried out with clinic midwives, midwife managers, medical staff and virologists. A letter explaining the project was sent to all GPs (annex appendix 1). Explanation of the study, with requests for opinion and advice was sent to patient organisations – the National Childbirth Trust (NCT) and the Association for Improvement in Maternity Services (AIMS).

On the basis of our results from the RCT, we recommended a leaflet containing information about all blood tests but including more information about HIV, specifying clearly the benefits of testing during pregnancy (annex appendix 2).

Again, on the basis of our results from the RCT, we recommended a minimal approach to discussion as it would cost less in terms of midwives' time, but it would still contain specific information on the benefits of testing (annex appendix 3).

The routine voluntary approach differed from the 'opt-in' approach in that women were told that the test was being done routinely and asked them whether they objected to the test being done (annex appendix 4). (In the 'opt-in' approach, women were told that the test was available and they were asked if they wanted it; see chapter 4 of the main report.)

A study afternoon was organised for midwives at which the following were explored:

- rationale for the study
- update on HIV issues
- discussion of the written protocol of HIV testing with the pregnant woman with an emphasis on the difference between an 'opt-in' and a routine voluntary approach

- possible questions and responses
- attitudes to HIV testing.

The target population was all women presenting for a first hospital visit between 2 February 1998 and 1 May 1998. Before the booking appointment, all of the women were sent material about the booking visit and this included a patient information letter and the leaflet about the blood tests, including HIV (annex appendix 2). At the clinic, they were offered an HIV test by midwives, who used the printed discussion protocol. As with the other tests, consent was given verbally. The midwives noted uptake, the time when discussion about the test started and when it finished, and whether the woman or her partner was at HIV risk from injecting drug use (annex appendix 5). After the consultation, women were asked to complete a questionnaire measuring attitudes, anxiety and reasons for taking or declining the test (annex appendix 6). This was basically the same instrument that had been used in the RCT, but slightly shorter because some material not directly relevant was omitted. The research midwife was based in the clinic and made sure that every woman had the opportunity to complete this questionnaire.

The data from this study are presented in the tables in the results section. For many results, we also present information from the RCT described earlier in this report. The different intervention groups are combined as 'opt-in' (n = 2030) because there were few substantial differences with different interventions. The control group (n = 994) comprised women to whom no routine offer of HIV testing was made. Differences between groups were examined with chi-squared tests for categorical data, analysis of variance for parametric data and Kruskal-Wallis analysis of variance for non-parametric data. There are possible changes in perception and behaviour of midwives and patients between the two studies and these are discussed below.

Results

Uptake of testing

In total, 924 women booked at the clinic, and of these 816 (88%) had an HIV test, which is a higher rate than in the previous 'opt-in' or control groups (*Annex Table 1*).

Prediction of uptake

There was no effect of age, marital status, partner's presence or having had a previous test on uptake when using the routine voluntary approach. Parity had an effect, with women having their first baby

ANNEX TABLE 1 Comparison of uptake rates for routine voluntary, opt-in and control groups

Approach	Uptake of testing
Control*	55/994 (6%)
Opt-in†	707/2030 (35%)
Routine voluntary‡	816/924 (88%)
Significance	$\chi^2 = 1413.6$, $df = 2$, $p < 0.0001$
* The test was available on request only	
† Information was given about testing and the woman was asked to choose whether or not she wanted test	
‡ Information was given about testing and testing was presented as routine, but the woman was given opportunity to decide not to test	

being more likely to take the test (*Annex Table 2*). Although the rates of clients' uptake of testing was fairly consistent among the 14 midwives who did some antenatal bookings during the study period, there were differences, the effect being of borderline statistical significance (*Annex Table 2*). The range was narrower when considering only those midwives who saw more than 50 women. There was no effect of geographical area of HIV risk on uptake of testing (*Annex Table 2*). There was an effect of social deprivation on uptake of testing, with those living in areas of deprivation more likely to take the test (*Annex Table 2*).

To summarise, the only demographic and situational factors affecting uptake were parity and social deprivation. Women who chose not to take the test were more likely to be women with children and women from more affluent areas. The midwife seen had an effect of borderline statistical significance.

Acceptability of a routine voluntary approach: women's response

The questionnaire response rate was 99% (916/924). As well as completing the form, many women gave additional helpful comments. None of the eight women who did not complete a questionnaire appeared to be upset by the offer of an HIV test, or the research study, or being asked to fill out a questionnaire. The most common reason given for not completing the form was lack of time because the woman had to rush off to another commitment.

The attitude to routine voluntary testing was assessed with the following question: 'Do you think the HIV test should be a routine test like all the other blood tests during pregnancy (i.e. it is done

ANNEX TABLE 2 The effect of demographic variables, previous testing and partner's presence on uptake of HIV testing when offered on a routine voluntary basis

Variable	No. (%) taking HIV test	Significance test
Age		$\chi^2 = 2.98, NS$
Older (≥ 30 years)	442/510 (90)	
Younger (< 30 years)	374/414 (87)	
Marital status		$\chi^2 = 0.25, NS$
Married	569/650 (88)	
Unmarried	183/206 (89)	
Parity		$\chi^2 = 4.25, p = 0.04$
Multiparous	405/470 (86)	
Primiparous	411/454 (90)	
Area risk code*		$MH\chi^2 = 0.94, p = 0.33$
1	40/44 (91)	
2	237/264 (90)	
3	99/114 (87)	
4	233/266 (88)	
5	180/206 (87)	
Social deprivation score†		$MH\chi^2 = 6.56, p = 0.01$
1	132/163 (81)	
2	148/169 (88)	
3	96/105 (91)	
4	212/234 (91)	
5	36/42 (86)	
6	25/27 (93)	
7	14/15 (93)	
Midwife		$\chi^2 = 22.2, df = 13, p = 0.05$
A	49/54 (91)	
B	33/42 (79)	
C	28/32 (88)	
D	87/98 (89)	
E	85/100 (85)	
F	21/26 (81)	
G	60/69 (87)	
H	52/62 (84)	
I	66/76 (87)	
J	107/115 (93)	
K	24/26 (92)	
L	75/76 (99)	
M	17/17 (100)	
N	112/131 (86)	
Partner's presence		$\chi^2 = 3.16, NS$
Present	496/552 (90)	
Absent	320/372 (86)	
Previous test		$\chi^2 = 1.22, NS$
Previously tested	90/98 (92)	
Not previously tested	648/736 (88)	
MH, Mantel-Haenszel		
* In Group 1 there are no HIV cases in the total population for the postcode areas included, whereas in Group 5 the rate is > 1 per 1000		
† Score 1 = highly affluent and score 7 = very deprived ¹⁰		

unless you say you don't want it)?'. In reply, 793 women (88%) said 'yes', 54 (6%) said 'no' and 57 (6%) said they were unsure. The opinions of those who said no or that they were unsure as to whether the test should be routine were elicited by asking for comments about how they thought the test should be offered, if at all. Quite a range of opinion and suggestions was obtained as detailed in *Annex Box 1*. Seventy-eight women of the 111 who had replied 'no' or 'unsure' responded to the opportunity for free text. Most of the answers were actually exploring definitions of ground between an 'opt-in' and a routine voluntary approach, and the question was perhaps not precise enough for some women. Thus the largest number (46) seemed to be suggesting things entirely compatible with the routine voluntary system used in the study (i.e. comments such as 'voluntarily', 'by personal choice', 'by consent', 'after speaking with the mother', '[the woman] should be consulted', 'optional', 'only if the person wanted the test done'). All of these women's views are encompassed by the current model of testing. This left 32 women who made suggestions for a different model of testing. These were that:

- testing only be performed on request (18 women)
- testing should be performed elsewhere, or by appointment (six women)
- issues around insurance had to be addressed (one woman)
- testing should be compulsory for all women (three women)
- there should be full counselling before testing (two women)
- only a selective offer should be made (two women).

The level of satisfaction with the consultation with the midwife was not affected by how women were offered the HIV test (*Annex Table 3*).

ANNEX TABLE 3 Comparison of satisfaction levels for routine voluntary, 'opt-in' and control groups

Approach	Mean (SD) satisfaction score*
Control (n = 865)	21.5 (3.4)
Opt-in (n = 1798)	21.5 (3.3)
Routine voluntary (n = 903)	21.7 (3.1)
Significance test	$KW\chi^2 = 0.71, df = 2, p = 0.70$
KH, Kruskal-Wallis	
* Maximum score possible = 25	

ANNEX BOX 1 Comments about how the HIV test should be offered, if at all, made by women who said 'no' or 'unsure' to the question about whether the test should be routine*

<p>I think it should be made available, but only on request.</p> <p>Voluntarily if the patient agrees when asked.</p> <p>Test should be made voluntarily.</p> <p>Available by request.</p> <p>It should be specifically offered.</p> <p>By personal choice.</p> <p>The test should be done only by consent.</p> <p>After speaking with mother concerned.</p> <p>Should be consulted first.</p> <p>Only if the person wanted the test done.</p> <p>By choice.</p> <p>Upon request.</p> <p>If the woman asks for it.</p> <p>On request as part of routine tests.</p> <p>Actively offered, but made clear that it is optional (like it was today).</p> <p>I think test should be offered and risk etc. discussed with patient. Think each case should be dealt with on own merits.</p> <p>Yes but up to each individual.</p> <p>By being offered at booking in clinic.</p> <p>If people are willing to get it done.</p> <p>Person's choice.</p> <p>This should be an option offered.</p> <p>Should be offered as an option.</p> <p>On request, but you should know it is available through info at hospital.</p> <p>I think the test should be readily available but there should be a choice whether to take it or not.</p> <p>Only if you want it.</p> <p>Freedom of choice/people who want it can have it.</p> <p>I think the test should be available if the patient chooses to take it.</p> <p>It should be up to the individual.</p> <p>Upon request.</p> <p>I believe the mother should be asked if she wants the test.</p> <p>On request or recommended.</p>	<p>Offer it as a test during pregnancy and give the option.</p> <p>The patient should be asked at first visit if they would like the test carried out or not (i.e. individual's choice).</p> <p>Yes, it should be offered and given with patient consent.</p> <p>Asked if you want it.</p> <p>By choice, possibly check for lifestyle (i.e. if activities place people in 'higher risk') . Counsel on advantage of testing and health of unborn baby.</p> <p>Voluntarily.</p> <p>On request.</p> <p>People should be aware that it is available, as now, and given the choice to say they want the test.</p> <p>It should be up to the individual to make the decision to have the test.</p> <p>Such a test always requires informed consent in my view. The present procedure re Down's testing seems optimal to me in terms of allowing balanced decision making.</p> <p>By choice.</p> <p>Available with no pressure.</p> <p>Own choice.</p> <p>Voluntary.</p> <p>Should always be given the chance.</p> <p>By choice of each individual.</p> <p>By choice.</p> <p>The way it is now – by asking.</p> <p>Should be offered in discussion with the midwife or GP (i.e. along with other information and screening tests).</p> <p>Offered but not made compulsory.</p> <p>By choice, with explanation of health benefits to unborn child.</p> <p>Mothers should be asked if they want the test.</p> <p>By consent.</p> <p>By asking the person concerned.</p> <p>It's up to the individual.</p> <p>Should be offered.</p> <p>It should not be done routinely but clients should know that it is available if wished.</p>	<p>By appointment only.</p> <p>As a separate consideration offered by your GP every few years.</p> <p>As part of GP's initial medical check when joining a practice or through work (i.e. hospital staff).</p> <p>? Pre-conceptually discussed as with rubella status</p> <p>Pre-natal – GP.</p> <p>You should have done it before getting pregnant.</p> <p>Offered to all and recommended strongly to those in high-risk groups.</p> <p>If people ask for the test or high-risk groups.</p> <p>Offered if person at risk.</p> <p>Only if a person has any worries.</p> <p>It should be available. But care has to be taken and counselling available for those in high-risk groups. There is no reason for an informed choice not to be made by each expectant mother.</p> <p>It should be available but perhaps with an option of counselling for those who feel they need it.</p> <p>They should stress the importance if you think you are at risk and leave the individual to decide – would say it is important to stress.</p> <p>If you are in a high-risk group.</p> <p>As public attitudes change it may be acceptable to be routinely test, problems with insurance companies would have to be addressed.</p> <p>I feel it should be offered, but patients should be offered full pre- and post-test counselling and 1 week is too long to await a result (i.e. GUM/HIV clinic obtain results in 1 day). And sending the result out by letter is quite worrying,</p> <p>I think it should be compulsory.</p> <p>Yes.</p> <p>Should be done regardless. Would let doctors know the full count on HIV.</p> <p>By just testing everyone by law!</p>
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* Questionnaire reproduced in annex appendix 6.

ANNEX TABLE 4 Comparison of anxiety levels for routine voluntary, 'opt-in' and control groups

Approach	Mean (SD) anxiety score*
Control (n = 830)	36.8 (10.8)
Opt-in (n = 1743)	36.4 (10.9)
Routine voluntary (n = 878)	33.2 (10.6)
Significance test	$F_{2,3448} = 32.2, p < 0.0001$
* Scores out of 24 are pro-rated to be out of 80 to be comparable with the original 20-item STAI scale (as in the main study reported above)	

Overall, anxiety levels following the clinic appointment seemed to be affected by how women were offered the HIV test. Women in the 'routine voluntary' group were less anxious (*Annex Table 4*).

The information given to women in the 'routine voluntary' protocol resulted in significantly greater specific knowledge about AZT than the information given in any of the 'opt-in' interventions. The only 'opt-in' intervention group that had equally high knowledge about breastfeeding in relation to HIV was the group who had received the comprehensive discussion and the detailed HIV leaflet (*Annex Table 5*). There are several possible confounders here as discussed later.

To summarise, the response to the routine voluntary approach was very positive. Most women thought the test should be routine

and this approach did not reduce satisfaction with the antenatal consultation. Moreover, anxiety levels were lower and knowledge was higher with this approach. As discussed below, these conclusions should be regarded with caution considering that this study was carried out 11 months after the RCT and is thus not strictly comparable with the previous intervention and control groups. However, it seems clear that the routine voluntary approach neither **increased** anxiety nor **reduced** knowledge.

Reasons given by women for taking and not taking the test

Women were given a choice of reasons and asked to report their most important reason for having the HIV test. Rather disconcertingly, the most common reason given was 'to help research'. The next most common reason was the feeling that it was a good idea to have it as a routine test and then because of actual concern about risks to the baby (*Annex Table 6*). Reasons given spontaneously for taking the test are shown in *Annex Box 2*. Women who did not take an HIV test mostly did so because they felt there was no chance that they were HIV positive (*Annex Table 7*). None declined because they were worried that they might be HIV positive. Twelve were worried about effects on insurance or mortgage (*Annex Table 7*). The reasons given spontaneously for not taking the test and the comments made by midwives (on the checklist for women who did not take the test) suggested that these were women at low risk, and there was no suggestion that those women who declined testing were doing so because of high-risk status (*Annex Boxes 3 and 4*).

ANNEX TABLE 5 Comparison of specific knowledge levels for all intervention groups

Group	Leaflet	Discussion with midwife	Breastfeeding knowledge [†] : no. (%) correct	AZT knowledge [‡] : no. (%) correct
1	None	None	263/865 (30)	128/865 (15)
2	'All blood tests'	Minimal	128/435 (29)	87/438 (20)
3	'All blood tests'	Comprehensive	284/468 (61)	190/470 (40)
4	'HIV specific'	Minimal	202/448 (45)	171/448 (38)
5	'HIV specific'	Comprehensive	309/446 (69)	243/446 (55)
6	Routine voluntary approach		619/904 (69)	628/905 (69)
Significance			$\chi^2 = 421.0, df = 5, p < 0.0001$	$\chi^2 = 665.2, df = 5, p < 0.0001$
Group 1 = control group; groups 2–5 = various 'opt-in' approaches (see main report)				
* This refers to the item 'a woman who has HIV can infect her baby through breastfeeding' (see annex appendix 6)				
† This refers to the item 'a pregnant woman who has HIV can reduce the chance of her baby becoming infected by taking zidovudine (AZT)' (see annex appendix 6)				

ANNEX TABLE 6 Frequency of reasons given for taking the HIV test

Reason	No. of women (%) reporting as most important reason*
To help research	315 (39)
It's a good idea to have it as a routine test	233 (29)
I was concerned about risks to the baby	122 (15)
Because it was offered	90 (11)
A midwife advised me to	25 (3)
I was concerned about my own health	8 (1)
I am/have been at risk of infection	5 (1)
My doctor thought it was a good idea	3 (0.5)
I was persuaded by family and/or friends	0

* The questionnaire is reproduced in annex appendix 6

ANNEX BOX 2 Other reasons given spontaneously for taking the test

You can never be sure about partner's health.
Thought it would be good to know for certain that I don't have it – put my mind at rest.
You never know do you?
Because of stigma it is not the sort of test you would feel you would ask for – but everybody worries about it.
So that it becomes a routine test.
I think everyone should have the test.
I was concerned about the risk to my baby and myself.
Just to be sure.
Midwife said it was routine to do so.
I thought it was good to have the test as part of routine testing rather than electing to have it done.
I feel it is important for every expectant mother to have one.
Because I have no pertinent reason to refuse a test.
If I was HIV, I would want to be the first to know so there wouldn't be any risk of transmitting it to my boyfriend.

ANNEX TABLE 7 Frequency of reasons given for not taking the HIV test

Reason	No. of women (%) reporting as most important reason*
It's not necessary as I've no chance of being positive	28 (30)
I've been in a stable relationship for a long time	15 (16)
I'm not in a high-risk group	14 (15)
I was worried about effects on insurance or mortgage	12 (13)
I would rather not know if I'm positive	9 (10)
I have been tested elsewhere	5 (1)
I don't want to think about HIV when I'm pregnant	5 (5)
Family and friends put me off having the test	4 (4)
I might be forced into a termination if positive	2 (2)
It was not offered to me	1 (1)
My partner has been tested elsewhere	0
I was advised not to by a midwife	0
I am worried that I might be HIV positive	0

* The questionnaire is reproduced in annex appendix 6

Time taken for routine voluntary discussion protocol (recorded by midwives)

The start and finish times were recorded for 918 out of the 924 consultations. The mean time taken was 2 minutes 34 seconds (SD, 1 minute 48 seconds). This was heavily skewed by some long discussions, and the median time was 2 minutes with the modal time being 1 minute.

Case finding

Of the 816 women who took a test in the routine voluntary study, one woman was found to be HIV positive. She had no risk features and, even after diagnosis, was not able to identify a drug using partner. She herself had never injected drugs. She would therefore not have been diagnosed in a selective testing programme, and perhaps not in an 'opt-in' programme.

One further woman who booked during the study was known to be HIV positive, so known prevalence was 2/816 (0.25%).

ANNEX BOX 3 Other reasons given spontaneously for not taking the test

I am already ineligible for many insurances (e.g. travel, health, life). As I consider I have no chance of being positive I see no potential benefits, only additional costs.

I believe that deciding to take a test for HIV requires a lot more thought and consultation than just being asked to think about it 1 week before your antenatal booking appointment. A positive result obviously has ramifications way beyond the relevance to pregnancy and I think specific support of counselling is necessary.

I wouldn't want it on my records that I've had an HIV test.

No I've learned to read about it and I have children to think about and I am too feared of the HIV. I would die. I've had all my jags for Hep.

If wish to take the test would prefer it to be carried out in a specialist unit when full pre- and post-counselling is given. I feel that this is a very important aspect of HIV testing.

Religion.

I don't take drugs and only had one man in my life. He is my husband.

Unable to say how litigation would affect me professionally.

I am under a lot of pressure at present and could not cope with a positive HIV test now. I'm also low risk. Also, job implications as a doctor.

I was tested during last pregnancy 18 months ago, my circumstances and my husband's have not changed.

I would not take the test until it is a routine test through the hospital and not only for pregnant women.

Too late – I have just moved to the area, baby is due in 4 weeks' time.

I don't want unnecessary tests and I'm not in a high-risk group.

Even though I have no concerns about the possibility of being HIV positive, I would be concerned about the effects on insurance or mortgage, having to declare that I had taken a test.

Although I know I can't be positive I didn't want to have to worry about another test result as I am anxious enough about abnormalities, etc.

Do not want to know.

Discussion

Effectiveness and acceptability of research studies in the antenatal clinic

From the practical point of view, this study, and RCT described earlier, were highly successful. Provided that there is appropriate training, and a written protocol, our experience has been that a small group of midwives will take part in such studies effectively and enthusiastically. Despite busy clinics, there were very few errors in allocating women to the long or short discussion in the RCT (and differences in timing showed that these interventions had occurred). The time taken was properly recorded in 918 out of 924 cases in the routine voluntary study. There were no extra clinical staff, and the midwife research worker, essential to the running of the study, was not clinically involved, no matter how overstretched the clinic was. Far from detracting from patient care, our feeling is that not only was information effectively transferred about HIV testing, but also that there were real improvements in communication about the other blood tests which are routinely performed.

Pregnant women were also accepting of the on-going research studies. Despite the sensitivity of the subject being examined, and the strongly held opinions that HIV often engenders, none of the women was very upset by the research study itself. There were no serious critical comments made to the midwives, or to the research midwife. There were no written complaints to the midwifery manager or to the Trust. There were no complaints relayed to us through GPs or patient organisations (NCT, AIMS). Thus, out of nearly 4000 participants, there was no suggestion that being part of a research study was perceived as a harm. Indeed, many women appeared positive about attempts to engage pregnant women's opinion in this way. The very high rates of completion of questionnaire (99% in the routine voluntary study) are supportive of this. In addition, the questionnaires were mostly completed carefully and consistently.

There have been few studies of any scale that have quantitatively examined presentation methods in the antenatal clinic. Our studies demonstrate that opinion and behaviour can be effectively and acceptably examined in this way. Indeed, provided that the aim is clearly seen to be improvement in care, these research techniques will be positively supported by midwives and pregnant women.

ANNEX BOX 4 Comments made by midwives on checklist for women who did not take the test

Feels sure she is not infected and worried about insurance, etc.

Has several chronic medical illnesses and unable to get travel and life insurance. Therefore does not want testing.

Routine testing in [country].

Unable to discuss, because present partner present. Not willing to have any screening.

Previous test when booking in [country].

Did wish to hear why we are offering HIV testing.

Worried about insurance companies asking – creating future problems getting insurance, etc.

If tested would prefer to be tested at 'specialised unit' and have pre- and post-test counselling.

Not discussed as HIV status known.

Declines as worried about implications re. insurance – is self-employed – and has to fill in insurance forms – which always ask if ever been tested for HIV.

Partner worried about insurance purposes.

Worried about insurance problems. Hep C +ve.

Patient would like to think about the HIV test and will inform her GP if she wants to have it done.

Does not wish testing. Aware of reasons for offering test antenatally but remains adamant she does not wish it.

Transferred at 37 weeks pregnant. Blood tests not being taken. Had no information in the post.

Would rather not know.

Had a long wait at the clinic. Previous test – thinks this was as part of research.

This lady was 32 weeks pregnant. I forgot to discuss HIV blood tests before venepuncture. I discussed it while taking blood for Hb. As blood test already done, and she was not concerned, she decided not have the test. Apologies.

Declined – considered herself not to be at risk, concerned re. litigation working in Health Service.

She said she did not want the test at start of discussion. Did not consider herself to be at any risk.

Felt no risk, been together since age 16. Partner donates plasma every 3 weeks, regularly tested.

Did not discuss – said she did not want test before discussion.

Declined test as soon as I mentioned the 'Blood testing leaflet'. Worried about implications on insurance and does not consider herself at risk.

Transfer at 35 weeks – had bloods done already. Did not wish blood taken for HIV only.

Refused to have any blood taken at clinic today.

Late booker at SMMP (transfer). Didn't have test – being admitted today for elective caesarean section.

Did not wish to take part in any more research. Concerned re insurance.

Patient had Hep C in 1992. Now cleared. Did not wish to discuss HIV – was aware of benefits of treatment.

Does not perceive herself at risk.

Had not received leaflet before visit – needed more time to think about it.

Did not wish to know HIV status.

Did not wish to discuss.

High-risk patient, chaotic lifestyle, refused all blood tests. Left before end of booking interview.

Previous test via GP.

Does not wish testing – could not give any particular reason.

Too worried about results of other tests.

Booking blood done by GP. Previous IUD at 16 weeks – wishing no screening or minimal testing.

Already booked – feels herself to be extremely low risk.

Felt that she was extremely low or no risk.

Unable to get any blood. Patient has needle phobia.

Effectiveness and acceptability of routine voluntary testing

One of the reasons why this approach was examined was because several pregnant women in the qualitative survey expressed an opinion that this would be easier for women, rather than their selecting themselves for testing. This method has received strong support from our study. Despite our anxieties beforehand, no women appear to have been upset by this presentation. Thus there were no complaints relayed through midwives, GPs or patient organisations or to research staff. The questionnaire was completed by 99% of women

and none of the eight women who did not complete a questionnaire appeared to be upset by the offer of an HIV test in this way (they were rushing off, late for an appointment). In all, 88% of women replied 'yes' to the statement, 'Do you think the HIV test should be a routine test like all the other blood tests in pregnancy (i.e., it's done unless you say you don't want it)?'. Of the 6% who replied 'no', most made suggestions that were really covered by the framework of the routine voluntary design and were seeking to define principles of testing more precisely, rather than being hostile to the method.

The routine voluntary model was compared for satisfaction, anxiety and knowledge with previous interventions (the RCT). In the routine voluntary study women were as satisfied, significantly less anxious, and had significantly more knowledge than women in the intervention groups in the RCT. Obviously, the data presented in this routine voluntary study are not from a randomised trial. There were no substantive differences between the populations (all pregnant women presenting for antenatal care) of the two studies. There were changes in midwives, with only the core group of three remaining the same. However, the consistency of uptake rates between midwives does not suggest that the big increase in uptake seen with the routine voluntary study can be explained by changes in personnel. However the study was performed 11 months after the RCT had finished. Although there had been no significant change in any of the outcome variables with time during the RCT, that study, once analysed and presented, may have altered perceptions of staff and patients. The RCT, along with other studies, was published shortly before the routine voluntary study started and there was considerable media coverage of the issues of HIV testing in pregnancy. We cannot therefore conclude that the significant differences observed were solely due to the method of presentation of testing. Nevertheless, there are plausible mechanisms why this might be true, and the data are reassuring in the sense that the routine voluntary approach has certainly not **increased** anxiety or **reduced** knowledge.

A concern about routine voluntary testing was that women might feel forced into taking an HIV test. This has not emerged as a problem in any of the informal feedback we have had, or in the questionnaires. The fact that 12% of women declined testing supports the belief that it was not difficult for women to do this.

Because all women have not yet delivered (and thus we are yet to analyse HIV test data from the unlinked anonymous HIV testing of neonatal metabolic screening cards), we do not know whether any women who declined testing were HIV positive. However, the reasons given for declining testing did not suggest that these women were at high risk. Because of the high take-up rate of testing, this model is likely to be more effective in terms of case finding than previous models.

This programme is thus acceptable to midwives and pregnant women, does not increase anxiety or reduce knowledge, and is likely to be effective.

Concerns that the concept of a routine voluntary programme may be misunderstood

There are concerns that such a routine voluntary programme may be used to test women without giving full information, or without their full understanding, or without their explicit informed consent. This is expressed using the analogy of ‘testing for syphilis, rubella and blood grouping, where most women are unaware that they are being tested’. This is thought to be a particular concern with the description ‘opt-out’, which we previously used. These are important concerns, but should not be directed at the type of programme or the name of the programme. We have seen that with a combination of written and verbal material a programme can be acceptable, informative, effective and not time-consuming. Indeed, as we have explained above, the standard of communication about other tests appears to have improved during the study. Because the partnership between carer and pregnant woman is basic to maternity care, good communication, full information and sharing of decision-making are fundamental requirements. The scenario described above is bad practice and unacceptable care. Women should not have any blood tests done and be unaware of what is being tested for. If this occurs, it is due to inadequate training or an inadequate ethos of care and is likely to be associated with other examples of bad practice. The response here should be to improve standards of care, not to blame the programme of testing. But it is also possible that these concerns are misplaced. Worry about standards of midwifery care, or how the name of a programme may be interpreted, are likely to be unfounded. The training and attitude of midwives in the UK mean that giving full information and seeking explicit consent is basic to their everyday practice. Managers need to ensure that there is adequate effective training, that there are clear written protocols, and that there is good patient written material. But then they should have confidence in the midwives to run the system.

However, in recognition of the concerns about the term ‘opt-out’, we have changed the description to the term ‘routine voluntary’, and will use this term in all publications.

How generalisable are the data?

The areas in the UK with moderately high prevalence of HIV in pregnancy are London, Edinburgh and Dundee. Edinburgh and Dundee are similar. There are particular differences in London, however, which are discussed below.

1. The majority of HIV-infected women in Edinburgh have acquired their infection through injecting drug use rather than sexual intercourse. There are only small numbers of women from ethnic minorities and language is an infrequent problem limiting communication. London has a large number of immigrants, sometimes refugees, with cultural and language difficulties, and HIV is predominantly found in these groups. This makes the issues of full information, assessing understanding and seeking explicit consent particularly problematical among these groups. Written information needs to be prepared in many different languages. Either midwives need to have the appropriate language and cultural awareness, or else translators and counsellors with a background in the relevant culture need to be available. Similarly, the services need to be available to cope with the wider ramifications of a positive diagnosis in an individual woman. There thus needs to be a community-based service which can follow through the implications within the family and wider community. Again, the issues of language and culture require particular support and preparation. Although these issues make the delivery of an optimal testing programme more difficult in an area with more widespread ethnic and language diversity than Edinburgh, this does not negate the principles of the testing programme described.
2. Most HIV-infected pregnant women in Edinburgh knew that that they were HIV positive before their pregnancy; in London the corresponding proportion of known infection has been about 20%. Accordingly the possibility of identifying infections previously undiagnosed is greater in London.
3. The model of antenatal care in Edinburgh is still that most women are 'booked' in the control hospital antenatal clinic by the same small number of midwives. This means that these specialist midwives are highly trained and experienced at delivering appropriate information. The fact that they are used to discussing HIV, are well informed, and have close back-up when required by medical staff and HIV counsellors, are obvious advantages. It is also easy to monitor performance. In some parts of London, antenatal care has been devolved to the community, so that large numbers of midwives book a very small number of pregnant women. This will make it difficult to ensure an adequate standard of information and understanding, difficult to incorporate new information and difficult to supervise and monitor performance. However,

this applies to all aspects of antenatal care, not just HIV, and an implicit responsibility of managers who are developing such an approach to antenatal care is to ensure that there is no reduction in the standard of care. This type of system of care will make the programme of testing we describe much more difficult, but this does not affect the principles involved.

The issues of level of hidden prevalence, ethnic and cultural heterogeneity and different systems of antenatal care will all make a testing programme more difficult in London. However, this does not affect the generalisability of the principles of our conclusions. We believe routine voluntary testing is appropriate provided that the safeguards of information, understanding, explicit consent and adequate follow-up services are fully in place.

What is the best type of programme?

We have tested several different types of programme including selective testing (control group), different types of 'opt-in' testing, and routine voluntary testing. All were underpinned by adequate information and interactive discussion with the midwives. All programmes were acceptable to women, although the routine voluntary programme had the strongest endorsement, the lowest anxiety, the most knowledge and the highest take-up of testing.

In terms of effectiveness (number of positive cases detected), it is again the routine voluntary approach, because of the high take-up of testing, which will be the most successful. The remaining consideration is cost. These programmes are not expensive compared with other screening programmes in pregnancy but, in terms of cost per child prevented from becoming HIV infected, the total cost is very high and it is doubtful (at the prevalence levels seen in the UK) if screening is cost-effective purely in terms of money saved treating an HIV-infected child. Decisions on appropriate screening programmes for different areas will, in our view, need to take into account hidden prevalence, the local cost of a programme and available resources. Our own opinion is that routine voluntary testing is the optimal model for areas of moderate prevalence (London, Edinburgh, Dundee) with the proviso that testing in bulk, with other tests, is carried out at low cost. These centres contribute more than two-thirds of the births to HIV-infected women in the UK. Our opinion is that areas of very low hidden prevalence, and this includes most of Scotland and England, should probably test selectively on risk assessment or patient request. This is because cost per child

avoiding infection under these circumstances is extremely high.

Decisions about this are not easy, and there will be changing circumstances, with alterations in prevalence and perhaps reduced costs of the assay in future. HIV testing need not be exceptional, and can be normalised to be part of routine antenatal testing. At the same time, it should not be exempt from the careful local assessment to which every screening test is subjected.

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.

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Annex appendix I

Letter sent to GPs



DEPARTMENT of OBSTETRICS and GYNAECOLOGY
Centre for Reproductive Biology
The University of Edinburgh
37 Chalmers Street
Edinburgh EH3 9EW
Fax 0131 229 2408
Telex 727442 (UNIVED G)
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18th December 1997

Dear General Practitioner

Assessing uptake and acceptability of a routine, opt-out approach to antenatal HIV testing

We are writing to inform you about a study soon to take place in the Simpson Maternity Hospital. It will involve all pregnant women who have an appointment to attend the ante-natal clinic for their booking visit from the beginning of February and, depending on numbers will probably finish at the end of April 1998.

As you are aware, the increasing optimism about the benefits of combination therapy for infected adults and the marked effect of Zidovudine in reducing mother to baby transmission are fuelling the pressure to increase the detection rate of HIV in pregnancy.

Over the past two years we have carried out a randomised controlled trial assessing the response to different methods of offering antenatal HIV testing, funded by the NHS Executive Health Technology Assessment Programme. For each of the different interventions an 'opt-in' approach was used, which means that the women were offered the test and were required to actively accept testing and give their formal written consent. The control group were not actively offered a test, but it was available if they wanted it. The trial has been very successful, in terms of assessment of opinion mainly due to the women's willingness to participate, and the main results are due to be published in the *BMJ* in January 1998.

However, not every HIV infected woman was identified and many women said they thought the test would be better to be done routinely along with the other antenatal blood tests. Such an 'opt-out' or routine approach to HIV testing (where the woman is told that the HIV test is being performed unless she objects) is established in the US and many countries in Europe. It is now being considered as a possible means of combating the low detection rate in the UK. However, the acceptability of an 'opt-out' approach among the women themselves needs to be assessed systematically and we have been successful in our application for extra funds from the NHS Executive to do this. The extension to our trial will allow us to compare the uptake and acceptability of the 'opt-out' approach directly with our existing findings from the 'opt-in' approaches and the control group.

All women will be sent an information letter about the study within their booking information package. They will also receive a leaflet about routine blood testing which includes a detailed section about the benefits of HIV testing. The clinic midwives will be trained to offer the test and will be given a standardised discussion protocol to ensure they cover the important information points with all women. Although the test will be offered in a positive way, each woman will be given the option to refuse and her decision will be respected. The research team will receive the results from the laboratory and negative results will be sent by post directly to the women within a week of testing. In the event of a positive or inconclusive result, the woman will be asked to come back to the clinic for further testing and counselling. As in the previous study, women's opinion will be sought through a questionnaire which they will complete at the clinic and which assesses knowledge, attitudes, satisfaction and anxiety.

Please get in touch with Dr Wendy Simpson on 0131 536 3213 or at the above address if you have any questions about any aspect of the study. We are also interested in your comments. We hope that the study will not cause any problems for you or your patients, but if it does, please do not hesitate to inform us as soon as possible.

Yours sincerely

Dr Wendy Simpson

Dr Frank Johnstone

Project Leader (psychologist)

Consultant Obstetrician

P.S. If you would like us to send you a copy of the *BMJ* paper or any of the other reports as they get published, please let us know.

Annex appendix 2

Blood tests leaflet

Screening tests in pregnancy
Part of caring for you and your baby

4. Syphilis

This sexually transmitted disease is now rare. We test for this because untreated syphilis can have very serious effects on the baby. Treatment of the mothers with penicillin will prevent these serious effects. There is therefore real gain for the occasional pregnancy affected.

5. Rubella (German Measles)

An infection with the rubella virus in the first 3 months of pregnancy causes abnormalities in most babies. Most women are now immune to rubella. Over 95% of our female population are immunised at school. If you have satisfactory levels of immunity, your baby is not at risk.

The purpose of the test is to confirm immunity. It will also identify women who are not immune so that they can have immunisation after delivery. Some women who have been immunised previously have low levels of immunity on testing. Such women are offered a "booster" immunisation after delivery.

Follow-up for Routine Blood Tests

If there is something you should know as a result of any of the tests, the midwives from the clinic will inform your GP. He/she will pass the information on to you and give you time to ask any questions you may have.

The result of your HIV test will not be given to your GP. You will receive it directly from the ante natal clinic.

If you have any questions about any tests please ask the midwife you see at the booking clinic

Other places where you can have the HIV test

HIV Counselling Clinic
City Hospital
For appointments and advice:
Telephone: 0131 536 6484

Genito-Urinary Medicine Clinic
Royal Infirmary of Edinburgh
For appointment or advice:
Telephone 0131 536 2104

If you wish they can offer you the result on the same day as you're tested.

Blood Testing at the Booking Clinic

Simpson Memorial Maternity Pavilion
The Royal Infirmary of Edinburgh
NHS Trust

As part of your care during pregnancy we offer you several blood tests. This leaflet explains the tests that are, or can be done on the sample of blood we will take from you at your booking visit.

Take time to read this information and note any questions you have. When you attend the clinic you can discuss these with the midwife.

Non routine blood test

Hepatitis B

At present, we don't routinely screen everyone for Hepatitis B. We can do this test easily if you want it, without giving you another needle prick.

This is a virus which particularly attacks the liver. It is much more common in some parts of the world (especially in Far East, Africa and parts of Asia), where the virus is usually spread from mother to child. It is also spread sexually or through injection drug use. We believe that few mothers in Edinburgh are carriers but we have no accurate information. Without a test, there is no way the mother herself will know whether she is infected.

Hepatitis B is relevant for pregnant women. If the mother is a carrier, her baby will probably become infected during delivery. A quarter of these children go on to have fatal liver disease. However, we can prevent most babies being infected by immunising them very soon after birth.

If your midwife or doctor think you are at risk, you will be offered this test.

If you are not offered the test, but would like to take it, please just ask your midwife.

Blood tests which are routine for all pregnant women at booking

1. Full Blood Count

This test sorts out and measures the cells in blood. The main purpose is to detect anaemia, a reduced number of red cells carrying oxygen through the blood system. However, sometimes the test may suggest other conditions such as shortage of iron or some types of hereditary abnormality.

2. Blood Group

This test tells us three different things about your blood:

- 1: whether you belong to group A, B, O or AB.
- 2: whether you belong to the Rhesus positive or Rhesus negative group. One in six women are Rhesus negative.
- 3: Whether there are any unexpected blood group antibodies in your blood as a result of a previous transfusion or pregnancy.

If you are Rhesus negative we will give you an injection called "anti-D" if you bleed during your pregnancy or if any invasive treatments are carried out, e.g. amniocentesis. After delivery of your baby we may want to repeat this injection. This is all explained in more detail in a booklet we will send you.

If you are Rhesus positive you will not hear from us.

3. HIV Testing

HIV infection can be passed from a mother to her baby during pregnancy or at delivery. The HIV test involves taking blood and testing it for antibodies to this virus.

If the blood test result is negative it usually means that the person is not infected with HIV. However it can take up to 3 months for the antibodies to HIV to appear. So, we advise further testing if the person thinks they may have been at risk of infection within the past three months. A positive blood result means that the person is infected with HIV. It does not mean that they have AIDS.

If we know that a mother is infected with HIV we can give her special care. This will help make it less likely that her baby becomes infected.

- Most importantly, she and her baby can have treatment with a drug called AZT which has been shown to reduce the chance of the baby being infected by two thirds.
- She can choose whether or not to breastfeed. HIV can be passed on by breastfeeding.
- She can choose to have a caesarean section. This may also reduce the chance of her baby becoming infected, but this is not proven.
- She can get treatment for herself and so protect her health and prolong her own life.
- She can make decisions about carrying on with the pregnancy. She may wish to terminate the pregnancy. However many HIV positive women have their babies and are happy about doing so.
- She can have safe sex using condoms to protect her partner and she can plan for the future. There are support groups for HIV positive women.

A negative HIV test does not affect past or future life insurance claims. If you choose to take the test, we will contact you by letter one week after testing with your result. If we need to recheck your blood test we will contact you sooner by phone and ask you to come back to the clinic to have the test repeated. This does not necessarily mean that the test is positive.

Annex appendix 3

Routine HIV testing: pre-test discussion

Routine HIV testing: Pre-test discussion

- Did you receive the leaflet about blood testing in the clinic?

If not - give leaflet to woman to read.

- As you'll have read in the leaflet, HIV testing is currently being carried out routinely, alongside all the other blood tests, because the HIV test is now being recommended by the Department of Health for all pregnant women.
- This is because early detection of HIV not only improves the outcome for those affected, but enables women to make informed decisions about their future, and that of their baby. If a woman is found to be HIV positive we can offer treatment and care during pregnancy, delivery and post-natally to reduce the chance of the baby being infected. Specifically, we can offer AZT which has been shown to reduce the risk of mother-to-baby infection by two-thirds. Also, because breast milk contains the virus, we would discourage HIV positive women from breastfeeding. We can also offer the woman treatment for herself which is likely to prolong her life.
- We know that most women are not at risk of HIV infection (the rate of infection in pregnant women in Edinburgh is currently about 1 in 1000). However, we also know from previous studies that only offering the test to women with risk factors (e.g. IV drug users) doesn't work. Some women who have been at risk may be missed out.
- The test is a simple blood test - it is tested along with the sample for rubella testing so we don't have to take any extra blood.
- Negative results will be sent out by post within a week. Very occasionally the test needs to be repeated. In this case, you would receive a phone call asking you to come in for further testing and discussion.
- Of course, as with the other tests we have talked about, you can choose not to be tested if that's what you would prefer.
- Do you have any questions?
- Do you have any objections to the test being done?

Annex appendix 4

Letter sent to pregnant women

January 1998

New Booking Clinic Mums
Antenatal Clinic
Simpson Memorial Maternity Pavilion
The Royal Infirmary of Edinburgh NHS Trust
Lauriston Place
EDINBURGH



Dear Mum-to-be

A study investigating the response to routine HIV testing in pregnancy.

You are probably aware that HIV infection continues to be a problem in Edinburgh.

We want to find the best method of making the HIV test available to pregnant women so that they are fully informed about the options available to them, but without making women unduly anxious. For women who test positive, there are now important benefits to themselves and their babies of knowing this in advance. However, we do need to find out how best to provide this service.

Over the past year we have been trying different methods of providing information about HIV to women attending the ante-natal clinic. The comments made by women suggest that many feel the test should be done routinely as long as there is the chance to say no. In response to women's opinions, we are now continuing our study in the clinic by investigating your response to routine HIV testing over a short period from February to the end of April 1998. At the clinic, the midwife will discuss the test with you and then will do the test along with the other routine blood tests unless you choose not to take it. She will, of course, answer any questions you may have. We want to know how you feel about the service so you will be asked to complete a brief questionnaire about HIV testing. Your responses will help affect how the service is offered to pregnant women in the UK in the future.

You can choose not to take an HIV test. In no way will this affect the quality or the nature of the care you receive in the clinic.

If you decide not to participate in the study by not completing a questionnaire, this will not affect the quality or the nature of the care you receive in the clinic.

If you have any questions about this study, please do not hesitate to ask the researcher in the ante-natal clinic - she will be happy to talk to you about it. We'd like to thank you in advance for the help you may give us in this important study.

Yours sincerely

Wendy Simpson
Project Leader

Annex appendix 5

HIV testing project: midwife protocol

Attach patient label here	<p>HIV Testing Project</p> <p>Midwife Checklist</p>
Midwife Code	_____
Patient AN Number	_____
Time started HIV discussion	_____ e.g. 10.42, 14.55
Time finished HIV discussion	_____
HIV test taken	Yes <input type="checkbox"/> No <input type="checkbox"/>
Partner present	Yes <input type="checkbox"/> No <input type="checkbox"/>
Previous HIV test (if known)	Yes <input type="checkbox"/> No <input type="checkbox"/>
IVDU present or past	Yes <input type="checkbox"/> No <input type="checkbox"/>
Partner or previous partner IVDU (if known)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Nationality and language if not English-speaking	_____
Comments	

Annex appendix 6

Booking visit questionnaire

University of Edinburgh
Department of Obstetrics and Gynaecology

Booking Visit Questionnaire

Date:					
Consultant:					

NHS Executive

PART 1

We are interested to know how satisfied you were with the standard of service in the antenatal clinic.

Please tick one box for each question.

1. The length of time waiting to see the midwife was ...

<input type="checkbox"/> poor	<input type="checkbox"/> satisfactory	<input type="checkbox"/> good	<input type="checkbox"/> very good	<input type="checkbox"/> excellent
-------------------------------	---------------------------------------	-------------------------------	------------------------------------	------------------------------------
2. The length of time you spent with the midwife was ...

<input type="checkbox"/> poor	<input type="checkbox"/> satisfactory	<input type="checkbox"/> good	<input type="checkbox"/> very good	<input type="checkbox"/> excellent
-------------------------------	---------------------------------------	-------------------------------	------------------------------------	------------------------------------
3. How easy it was to ask the midwife questions was ...

<input type="checkbox"/> poor	<input type="checkbox"/> satisfactory	<input type="checkbox"/> good	<input type="checkbox"/> very good	<input type="checkbox"/> excellent
-------------------------------	---------------------------------------	-------------------------------	------------------------------------	------------------------------------
4. How well the midwife answered your questions was ...

<input type="checkbox"/> poor	<input type="checkbox"/> satisfactory	<input type="checkbox"/> good	<input type="checkbox"/> very good	<input type="checkbox"/> excellent
-------------------------------	---------------------------------------	-------------------------------	------------------------------------	------------------------------------
5. The relevance of the information you received from the midwife was ...

<input type="checkbox"/> poor	<input type="checkbox"/> satisfactory	<input type="checkbox"/> good	<input type="checkbox"/> very good	<input type="checkbox"/> excellent
-------------------------------	---------------------------------------	-------------------------------	------------------------------------	------------------------------------
6. Overall, how would you rate your session with the midwife?

<input type="checkbox"/> poor	<input type="checkbox"/> satisfactory	<input type="checkbox"/> good	<input type="checkbox"/> very good	<input type="checkbox"/> excellent
-------------------------------	---------------------------------------	-------------------------------	------------------------------------	------------------------------------
7. If you saw a doctor, how would you rate your session with the doctor?

<input type="checkbox"/> poor	<input type="checkbox"/> satisfactory	<input type="checkbox"/> good	<input type="checkbox"/> very good	<input type="checkbox"/> excellent
-------------------------------	---------------------------------------	-------------------------------	------------------------------------	------------------------------------

8. Please let us know if there was any specific thing about your booking visit that you were not happy about.

PART 2

1. a. Did you take the HIV test?

<input type="checkbox"/> yes	<input type="checkbox"/> → if yes, please go to question 2
<input type="checkbox"/> no	<input type="checkbox"/> → if no, please turn over to question 5
<input type="checkbox"/> don't know	<input type="checkbox"/> → if don't know, please go straight to part 3
2. Following is a list of reasons for taking an HIV test that people sometimes give.

What is your most important reason for taking the test?

_____ Choose a letter from the list below

_____ Choose a letter from the list below

- A I was concerned about risks to the baby
- B I was concerned about my own health
- C I am/have been at risk of infection
- D I was persuaded by family and/or friends
- E my doctor thought it was a good idea
- F a midwife advised me to
- G to help research
- H because it was offered
- I it's a good idea to have it as a routine test

You may have other reasons for deciding to take the test which are not listed above. If so, please write them here.

3. What kind of result do you expect?

<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> unsure
-----------------------------------	-----------------------------------	---------------------------------
4. Do you have any regrets about taking the test?

<input type="checkbox"/> yes	<input type="checkbox"/> If yes, why? _____
<input type="checkbox"/> no	<input type="checkbox"/> _____

NOW GO TO PART 3

5. Following is a list of reasons for not taking the HIV test that people sometimes give. Why did you decide not to take the test?

What is your most important reason for not taking the test?

Choose a letter from the list below

Do you have another reason? If so what is it?

Choose a letter from the list below

- A I would rather not know if I'm positive
- B I don't want to think about HIV when I'm pregnant
- C I was worried about effects on insurance or mortgage
- D I was advised not to by a midwife
- E I might be forced into a termination if positive
- F I am worried that I might be HIV positive
- G family and friends put me off having the test
- H it's not necessary as I've no chance of being positive
- I I've been in a stable relationship for a long time
- J I have been tested elsewhere
- K my partner has been tested elsewhere
- L I'm not in a high risk group
- M it was not offered to me
- N I didn't want to wait for a week for the result

You may have other reasons for choosing not to take the test which are not listed above. If so, please write them here.

PART 3

Here are some questions about HIV, AIDS and the HIV test.

Do you agree or disagree with the following statements about HIV and AIDS?

Please tick one box for each question.

1. If someone gets a positive HIV test result, it means that they have AIDS.
 - agree
 - disagree
 - unsure
2. HIV is a virus which causes AIDS.
 - agree
 - disagree
 - unsure
3. A pregnant woman who has HIV can reduce the chance of her baby becoming infected by taking Zidovudine (AZT).
 - agree
 - disagree
 - unsure
4. A woman who has HIV can infect her baby by breastfeeding.
 - agree
 - disagree
 - unsure
5. A person can be infected with HIV and look well.
 - agree
 - disagree
 - unsure
6. How can you become infected with HIV?
 - a. By kissing someone who is infected with HIV?
 - yes
 - no
 - unsure
 - b. By having unprotected sexual intercourse with someone who is infected with HIV?
 - yes
 - no
 - unsure
 - c. By giving a blood donation at a blood donor centre?
 - yes
 - no
 - unsure

6. (cont.) How can you become infected with HIV?

d. By a mosquito bite? yes no unsure

e. By sharing needles for injecting drugs with someone who is infected with HIV? yes no unsure

f. By being in a swimming pool with someone who is infected with HIV? yes no unsure

7. Do you feel you know as much about HIV and AIDS as you want to know? yes no

8. How likely do you think it is that you are infected with HIV?

Please circle a number between 1 and 5

1 2 3 4 5
very likely very unlikely

9. a) Do you think that 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)?

yes no unsure

b) If you said no or unsure, how do you think the test should be made available, if at all?

PART 4

A number of statements which people have used to describe themselves are given below. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer that seems to describe your present feelings best.

Read each statement and then circle the most appropriate number to the right of the statement to indicate how you feel right now.

- | | | | | |
|--------------------------|-----------------|---------------|-----------------|----------------|
| a. I feel calm | not at all
1 | somewhat
2 | moderately
3 | very much
4 |
| b. I am tense | not at all
1 | somewhat
2 | moderately
3 | very much
4 |
| c. I feel upset | not at all
1 | somewhat
2 | moderately
3 | very much
4 |
| d. I am relaxed | not at all
1 | somewhat
2 | moderately
3 | very much
4 |
| e. I feel content | not at all
1 | somewhat
2 | moderately
3 | very much
4 |
| f. I am worried | not at all
1 | somewhat
2 | moderately
3 | very much
4 |

Please make sure that you have answered all the questions.

Thank you very much for your time. Your answers are very important for helping us improve the service and care in the clinic.

Health Technology Assessment panel membership

This report was identified as a priority by the Population Screening Panel.

Acute Sector Panel

Current members

Chair: Professor Francis H Creed, University of Manchester	Dr Katherine Darton, M.I.N.D. Mr John Dunning, Papworth Hospital, Cambridge	Ms Grace Gibbs, West Middlesex University Hospital NHS Trust	Dr Duncan Keeley, General Practitioner, Thame
Professor Clifford Bailey, University of Leeds	Mr Jonathan Earnshaw, Gloucester Royal Hospital	Dr Neville Goodman, Southmead Hospital Services Trust, Bristol	Dr Rajan Madhok, East Riding Health Authority
Ms Tracy Bury, Chartered Society of Physiotherapy	Mr Leonard Fenwick, Freeman Group of Hospitals, Newcastle-upon-Tyne	Professor Mark P Haggard, MRC	Dr John Pounsford, Frenchay Hospital, Bristol
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Ms Lynne Clemence, Mid-Kent Health Care Trust	Professor Adrian Harris, Churchill Hospital, Oxford	Professor Jon Nicholl, University of Sheffield	Professor Kenneth Taylor, Hammersmith Hospital, London
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