Cluster-randomised trial of risk communication to enhance informed uptake of cervical screening

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SUMMARY

Background: *Women overestimate both population and individual risk of cervical cancer. This may contribute to the recognised excess screening frequency for low-risk women.*

Aim: *To investigate whether an individualised risk communication package could affect stated preferences for screening interval and actual screening behaviour.*

Design: *Pragmatic, practice-based cluster randomised controlled trial.*

Setting: *Twenty-nine practices (15 intervention, 14 control) in North Wales recruited 1890 women attending for cervical smears.*

Method: *A risk communication package containing visual material was compared with normal practice. Practice nurses received training in its delivery. The short-term primary outcome was stated preference for screening interval; the long-term primary outcome was actual screening behaviour.*

Results: *In the short term, intervention arm women were significantly less likely to prefer a shorter than recommended interval (odds ratio [OR] = 0.51, 95% confidence interval [CI] = 0.41 to 0.64; P<0.0001). At the five-year follow-up, fewer women in the intervention arm had attended for screening sooner than their recommended recall. The magnitude of difference in excess screening interval preference and behaviour was similar, but behaviour had a wider confidence interval and a marginally non-significant P-value (OR = 0.61, 95% CI = 0.36 to 1.03; P = 0.063). Better knowledge and more accurate risk perceptions were demonstrated, with an improvement in measures of anxiety. The extra cost per woman receiving the intervention was £6.*

Conclusions: *Women's perception of risk contributes to determining screening intervals in addition to practice factors. Simple risk information delivered in primary care affected women's stated preferences for tests. The impact on actual screening behaviour was more equivocal. Overall, the intervention showed a substantial benefit and any disbenefit can be ruled out. This approach to providing risk information could, at low cost, benefit other screening programmes and may relieve anxiety.*

Keywords: *cervical screening; risk perception; randomised cluster controlled trial.*

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Submitted: 9 April 2002; Editor's response: 1 July 2002; final acceptance: 24 February 2003.

Introduction

THE National Health Service Cervical Screening Programme (CSP) has reached 80% coverage.[1] But this costly programme[2] would work more effectively if resources were more accurately targeted to need.[3] There appears to be substantial over-screening of low-risk women, compared with those at highest risk.[4] There is evidence that psychological morbidity may be sequelae of screening, and there are calls for honest and high-quality information for women.[4-6]

The government recommends a five-year interval for women with a normal screening history; most areas have reduced this to three years.[1] Excessive testing (defined here as tests for women with no previous abnormality at intervals of less than three years) was as high as 40% in Wales,[3] and 15% in a Manchester sample.[7] The reasons for excess testing are likely to be numerous. Part of the variation appears to be owing to the smear takers, with 18% of the practices in the Manchester sample carrying out 50% of excess tests.[7,8] The reasons for practice variation remain unclear, though practitioner effects are unlikely to be the sole explanation.

Consumer preferences for additional screening tests are poorly understood. The National Screening Committee has stated that '… there should be evidence that the complete screening programme … is clinically, socially and ethically acceptable to health professionals and the public'.[9] Medical and lay perspectives of the purpose of screening are known to be diverse.[10,11] While the medical aim of screening is predominately to seek out, diagnose and treat, the lay aim is more concerned with reassurance about the present and the future. This is one of the reasons why attention is shifting away from simply increasing the uptake of smear tests to promoting informed consent and informed uptake.[2,12,13]

Work in South Wales preceding this trial revealed that women greatly overestimate their risk of cervical cancer.[3] The wish for frequent repeat tests was revealed by a pilot study. A sample of 245 women with a normal cytological history attending one South Wales practice for any reason completed a questionnaire. A majority (57%) stated that they would ideally prefer their smear tests at 12 month intervals or less. This preference may be part of the reason that excess testing occurs.

Moreover, the method and ethics of communicating risk need further research.[14,15] New methods of communication should foster partnerships between health professionals and patients for decisions on both existing and proposed screening programmes. A systematic review of risk communication revealed a pressing need for randomised controlled trials, noting that larger effects might be expected for interventions including elements of individualised risk communication.[16]

HOW THIS FITS IN

What do we know?

The cervical screening process causes psychological morbidity and there is evidence that women attend more frequently than the recommended screening interval.

What does this paper add?

Simple, low-cost, individualised risk communication materials can alter risk perceptions, knowledge and intention to seek early screens, and may be borne out on screening behaviour.

To address these dilemmas for cervical screening from a primary care perspective, a pragmatic practice-based randomised controlled trial was conducted to assess a risk communication package designed to reduce fear and raise awareness, by giving accurate, simple and personalised information. The economic evaluation is reported in full elsewhere.[17]

Method

Recruitment and allocation

This trial was conducted in North and South Clwyd, with the North Wales Health Authority (Wrexham and Glan Clwyd) local Research Ethics Committee approval. Between November 1995 and May 1996, 43 group general practices were contacted, of which 32 (74%) agreed to take part in the trial. Randomisation by practice (stratified according to number of partners; between two and four, or over four, partners) was performed using computer-generated sequences by one of the authors (TJP) not involved in practice recruitment and blinded to practice identity by the use of practice codes. Of the 32 practices randomised, 29 (67%) recruited women to the trial (15 in the intervention group and 14 in the control group). Three practices withdrew post-randomisation from the intervention group, owing to staff restructuring and changing practice nurse roles.

Between July and December 1996, women were recruited while attending for their routine cervical smear test. During the index consultation, the woman's eligibility was established (that is, they had not had a dyskaryotic, borderline or inadequate result on the preceding smear), an information sheet was provided and consent obtained. The intervention was then administered according to usual practice. Following the consultation, a questionnaire was completed before leaving the surgery. A small number required a postal reminder but all were completed prior to receipt of the smear test result.

Cytology results for all women who participated in the trial were followed up over a period of four years to determine their actual screening interval. Laboratory and Health Authority databases were searched for individual smear histories.

Sample size

Given national and local policies, the 'generally appropriate' interval for this trial was three to five years. If 40% of women attend at inappropriately short intervals,[18] then to detect a change of 10% (that is, a reduction to 30%) with a two-sided 5% significance level and 90% power, 477 women were required in each arm of the trial if randomisation was by individual. For practice-based randomisation, assuming a mean cluster size of 150 women per practice and a mean and variance for the proportion attending inappropriately of 40% and 5% respectively,[18] the resultant inflation factor was 1.6[19] and the total sample size was therefore inflated to 1526, or 763 in each arm. To account for 12% attrition this was increased to 850, yielding a total target number of 1700 women. At 150 women per practice, this required 12 practices in total. For logistical reasons it was decided to approach all eligible practices in the study area and recruit for a shorter period of time, but to retain the target total of 1700 women to increase the study power.

The intervention

The intervention comprised a brief specific counselling session designed to take approximately ten minutes. It was intended that this would replace the usual information and to be integrated with the smear test appointment. Delivered by the smear taker, it comprised risk communication materials identifying women's perceptions of risk, using both a previously validated personalised risk score and population information.[18] Both relative and absolute risks were portrayed in pictures and numbers, and appropriate follow-up screening intervals were negotiated. Intervention practice nurses and general practitioners were trained in the use of the pack in a number of sessions.

Outcome measures

The short-term primary outcome measures were: stated preference for future screening interval; five modified Likert scales assessing screening-related anxiety/concerns; two measures of risk perception (one personal, one population); and two objective measures of anxiety/mental health (the Spielberger State Anxiety Index[20] and the mental health dimension of the SF-36[21]). The stated preferred interval was obtained as an ordered categorical variable with six options but for the primary analysis this was dichotomised *a priori* to 12 months or less versus more than 12 months, to identify a group of women for whom the intervention was most relevant. The intervention was costed to include training (trainer and trainee time, travel and materials), intervention materials and extra consultation time as reported by women. Staff time was valued at gross employment cost. All costs have been adjusted to year 2000 prices using the NHS Pay and Price Index.

The long-term primary outcome measure was actual screening behaviour, in particular, whether or not the woman's next smear test was carried out earlier than the date corresponding to the interval recommended for her (usually three years but sometimes 12 months or less).

The 21 secondary outcome measures (all short-term) related to five general aspects of knowledge and psychosocial wellbeing. These comprised: three Likert-type items regarding sexual health, reproductive health and general health; three variables reflecting knowledge of absolute risks of an abnormal smear result and of cervical cancer, and knowledge that a normal smear result does not completely rule out abnormalities; the Impact of Events Scale (total and two subscales[22]); the remaining seven dimensions of the SF-36; and an assessment of patient satisfaction (the overall score and

four sub-scores of the Consultation Satisfaction Questionnaire[23]).

Data analysis

First, descriptive statistics were used to consider the representativeness of the women recruited to the trial and to assess baseline comparability of the two trial arms. The principal analyses were all performed on an intention-to-treat basis, comparing the women in the intervention and control groups as randomised, after allowing for clustering effects at a practice level by using random effects regression models.[24] Estimates, 95% confidence intervals, and *P*-values for these comparisons were obtained using regression models for the continuous outcome variables and logistic regression for binary outcomes.[25,26] The dichotomies for the latter were selected in advance of comparing the trial arms, and were based for each variable on a combination of clinical grounds and the overall distribution of responses. The only secondary analysis performed was a planned subgroup analysis using regression models to investigate differential intervention effects on the primary outcomes in terms of baseline risk status, as either 'very low risk' or 'low risk' from a risk score based on four risk factors.[18]

Results

Recruitment of practices and women, participant flow and follow-up

From trial records, 1978 women were approached, of whom only 88 refused (Figure 1). From 29 practices, 1890 women were therefore recruited to the trial, 1118 and 772 from the control and intervention practices respectively. These numbers are unequal as a consequence of randomisation by practice rather than by individual woman, despite broad stratification by practice size. The respective numbers of women returning the questionnaire were 951 (85%) and 704 (91%), with actual screening behaviour at five years available for 829 (74%) and 630 (82%) (Figure 1).

It was not considered feasible to monitor all women who attended these practices and were eligible for the trial but were not invited to participate, either because the study nurse was not present or she failed to invite the woman. Instead we have estimated the number of eligible women from routine data. For women registered with the 29 practices, Health Authority and screening laboratory data indicates that approximately 6500 tests were processed by the CSP between July and December 1996. Assuming that 20% of these were outside the practice setting, that of those taken within the practices 80% were by the practice nurses, and that 20% of the remainder were from women without a normal smear history, then this implies a total of approximately 3300 relevant smear tests for these practices. Only 36 of the 53 practice nurses took part in the trial, which yields an estimated 2242 eligible women. Based on these estimates, 88% of women who were eligible for the trial were approached by practice nurses and 84% were recruited. The eventual sample was similar to that expected for those attending for cervical screening, with the younger age bands over-represented compared with all women in the screening age range.

Baseline comparability

There were no marked differences between intervention and control groups in terms of sociodemographic characteristics or risk status (Table 1). Therefore, as expected, the unequal sample sizes have not resulted in any systematic differences between the two groups.

Primary outcomes: stated preferences for screening interval and actual screening behaviour at five years

The intervention brought a substantial number of women's desired screening intervals closer to that recommended by the NHS CSP (44% in the intervention arm desired a screening interval of 12 months or less, compared with 61% of women in the control arm). From the logistic regression model this comparison had an odds ratio of 0.51, which remained statistically significant after correction for clustering (Table 3).

The long-term outcome measure of actual behaviour was available for 1459 (77%) women, with 7% of 829 women and 5% of 630 women having shorter than recommended intervals, in the control and intervention groups respectively. Of the remaining 196 women, 51 had moved from the health authority area or emigrated, seven had died, 106 were cancelled from the NHS CSP (for example, hysterectomy or aged over 60 years), 24 could not be analysed owing to no recorded recall date, and eight were untraceable. The odds ratio of 0.61 in Table 3 is in favour of the intervention group, and although the conventional level of statistical significance was just not reached, the confidence interval rules out odds ratios that substantially favour the control group.

Other short-term primary outcome measures

The findings for the five Likert-type scales for anxiety, concerns and fears regarding the disease and the screening programme were more equivocal. Nevertheless, three of them were marginally statistically significant in favour of the intervention (albeit with upper confidence limits approaching unity) and for most of the outcome measures there was no suggestion that anxiety levels were appreciably higher in the intervention group (Table 4).

There was no effect on perception of personal risk (although the confidence interval was relatively wide), but there was a large, highly statistically significant improvement in accurate knowledge of the small population risk of cervical cancer. In the control practices, 85% of women incorrectly judged that cervical cancer was among the top four female cancers in the United Kingdom, compared with 22% in the intervention group. The intra-practice correlation was much larger for this outcome than for the other measures (Table 4), reflecting a marked influence of the practice nurse for this outcome. This is reinforced by the observation that almost all the inter-practice variation was found among the intervention practices (intra-cluster correlation coefficient [ICC] = 0.25) rather than the control practices (ICC = 0.0018).

In terms of the objective measures of anxiety and mental health (Spielberger State Anxiety Index and the mental health dimension of the SF-36), adjusting for clustering led

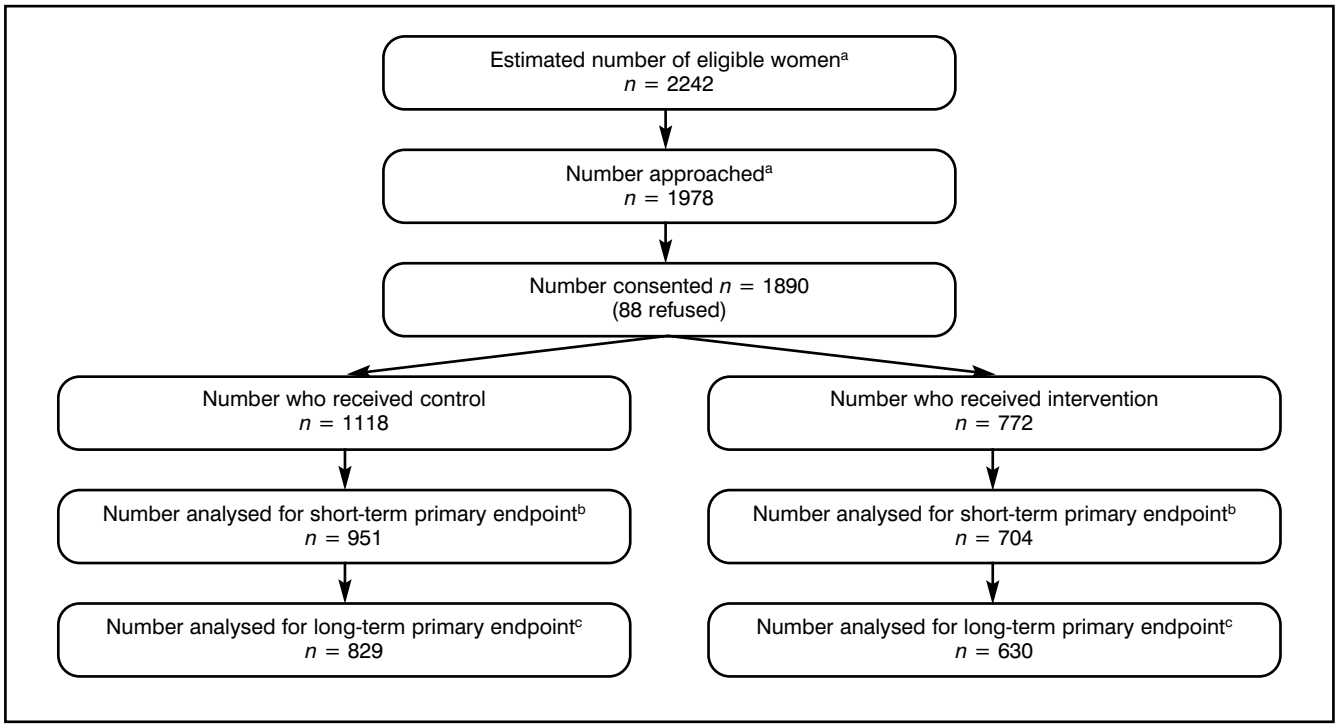

Figure 1. Trial profile. [a]See Method. [b]Those that had returned the questionnaire. [c]Cytology data available or recommended screening interval already elapsed (see text for details).

Table 1. Sociodemographic characteristics[a] of participating women, according to randomisation group.

	Control (*n* = 951)	Intervention (*n* = 704)
Age in years, mean (SD)	42 (13)	41 (12)
In active employment (%)	56	64
Educational qualifications to A-level or above (%)	17	17
Current smokers (%)	24	24
Used oral contraceptives for 5 years (%)	38	39
Number of sexual partners (%)		
1	46	44
2	17	23
3 or more	37	33
Risk classification (%)[b]		
Very low risk	78	80
Low risk	22	20

[a]The proportion of responders with missing data on individual items was less than 3% in all cases. [b]From an overall risk score based on the preceding four items in this table, dichotomised as determined previously to 'low risk' and 'very low risk'.[16]

to differences between the groups of -1.6 (95% CI = -3.5 to 0.2; *P* = 0.084) in favour of the intervention and 0.004 (95% CI = -3.0 to 3.0; *P* = 0.99), respectively.

The total cost of five training sessions was £2714 (mean cost/trainee = £90, range = £81 to £114). The total cost of intervention materials was £727; the mean cost per intervention woman was thus £4.89. The difference in mean consultation time (intervention minus control) was 1.71 minutes (95% CI = 0.86 to 2.57) valued at £1.12. The total intervention cost per woman was thus £6.01. Sensitivity analyses showed little effect on costs by varying assumptions, such as training and consultation time.

Short-term secondary outcomes

Of the 21 secondary outcome measures only two were statistically significant, either before or after applying a Bonferroni correction for multiple testing.[26] These were the two measures of knowledge of absolute risks, where the odds ratios of realistic perceptions of risk for intervention compared with control women were 0.53 (95% CI = 0.36 to 0.78) for the risk of an abnormal smear and 8.7 (95% CI = 5.5 to 13.7) for the risk of cervical cancer. The impact of the intervention is therefore in opposite directions for these two outcomes; the intervention appeared to improve realisation that cancer is rare (in the same way as measured by the relevant primary outcome in Table 4), but at the same time led to an underestimate of the risk of an abnormal smear. For none of the remaining secondary outcomes was there any evidence of an intervention effect.

Secondary analyses

The subgroup analyses according to baseline risk status were performed by introducing the interaction between study arm and risk status into the regression model for each primary outcome in turn. Of the 11 tests performed, only one was statistically significant. There was a suggestion that the benefit from the intervention in terms of self-reported gynaecological health was apparent only among the 80% of women who were in the very low risk category (OR = 0.19 for these women and 1.5 for the remainder; *P* = 0.0045 for the relevant interaction term).

Discussion

Summary of main findings

This trial demonstrated that a majority of women who have never had an abnormal test still perceive cervical cancer to be far more common than it is, and wish to have their tests

at intervals which are unrealistically frequent for the NHS CSP. A simple risk communication intervention delivered by the primary care team significantly reassured women and left them feeling more comfortable with a three-year interval between tests. Moreover, women appear not to have been falsely reassured.

The risk communication intervention had a marked impact both on women's stated preferences to seek excessively frequent screening tests, and on practice nurses' behaviour in relationship to these women. Although slightly more equivocal in terms of statistical significance, there may also be benefits for actual screening behaviour; however, these are unlikely to be substantial. Certainly, a disbenefit for the intervention can be ruled out in respect of subsequent screening intervals. Moreover, the magnitude of the association is very similar to that for the stated preference for screening interval.

In the short term, the intervention markedly improved knowledge, particularly about population levels of risk of cervical cancer. The control group's gross overestimate of population risk of cervical cancer is not surprising given previous public health campaigns, frequent media scares, and the conceptual difficulty of distinguishing cervical intraepithelial neoplasia from invasive cervical cancer. The longer-term impact on risk perception, knowledge and psychosocial wellbeing will be reported separately.

At £6 per woman, this is a relatively low-cost intervention. Moreover, the cost per woman for training and materials (£4.89) will fall significantly as more women receive the intervention. Costs will also be dependent on the way training is delivered.

Table 2. Distribution of stated preference for next screening interval by randomisation group.

Category of stated preference	% Control (n = 930)	Intervention % (n = 687)
6 months	9.0	4.4
12 months	52.0	40.0
2 years	21.5	27.9
3 years	13.4	25.0
4 years	0.9	0.6
5 years	3.1	2.0

Agreement/disagreement with the existing literature

A trial of a similar risk communication package applied to women under surveillance for a mildly abnormal smear revealed smaller effects.[27] The high and persistent nature of anxiety among such women leaves a concern that, on balance, surveillance may not be the best management for them.

A recent review in this journal[32] suggested that increasing the interval to five years and concentrating on quality improvements in the CSP would be an example of sensible rationing of limited resources, but stops short of suggesting how this might be achieved or enforced. The authors call for a debate with all stakeholders.

Strengths and limitations

Differences in numbers between the intervention and control groups, as a result of cluster randomisation, did not affect comparability between the two groups (Table 1). There may be a small loss of power, but in any event the practice was incorporated into the analysis as a random effect.

The only evidence of sub-group effects was for the outcome of self-reported gynaecological health. While chance

Table 3. Comparison between control and intervention groups in terms of stated and actual screening interval, allowing for clustering by practice.

Outcome variable	Odds ratio[c]	95% CI	*P*-value	ICC
Stated preference for next screening interval to be 12 months or less[a]	0.51	0.41–0.64	<0.0001	0.031
Actual screening interval shorter than that recommended for the individual woman[b]	0.61	0.36–1.03	0.063	0.014

[a]Stated preference: control (n = 951), intervention (n = 704). [b]Actual behaviour: control (n = 711), intervention (n=554). [c]Odds ratios are for a worse outcome status, for intervention compared with control women; all statistically significant comparisons are in favour of the intervention (OR<1). ICC = Intra-cluster correlation coefficient.

*Table 4. Comparison between control (*n *= 951) and intervention (*n *= 704) groups in terms of the remaining short-term primary outcomes, allowing for clustering by practice.*

Outcome variable (worse category)	Odds ratio[a]	95% CI	*P*-value	ICC[b]
Anxious about recent smear test (little/very)	0.81	0.66–0.98	0.036	0.001
Concerned about smear result (very)	0.75	0.45–1.24	0.25	0.0096
Perception of gynaecological health (very/fairly poor)	0.43	0.19–0.99	0.048	0.012
Concerned about chances of serious problems with smear test in the future (little/very)	0.70	0.51–0.95	0.026	0.024
Fearful of cervical cancer (quite/very)	0.66	0.47–0.93	0.019	0.030
Perceived personal risk of cervical cancer (high compared with personal risk[c])	1.07	0.85–1.35	0.57	0.0006
Perceived population risk of cervical cancer (consider cervical cancer to be one of the four most common female cancers in the UK)	0.05	0.02–0.11	<0.0001	0.47

[a]Odds ratios are for a worse outcome status, for intervention compared with control women; all statistically significant comparisons are in favour of the intervention (OR<1). [b]Intra-cluster correlation coefficient. [c]See Table 1.

may explain this finding, the direction of the interaction is highly plausible in clinical terms — that is, that the intervention should be particularly effective for the large group of women who experience concerns about gynaecological health on attending for screening but who are nonetheless at very low risk of an abnormal test result.

The results of this trial need to be seen in the broader context of the overall worth and cost of the cervical screening programme. This is an expensive programme with limited evidence of effectiveness, the test has a poor false-negative rate and the disease is very rare. Therefore it is not surprising that debate recurs about whether cost-effectiveness should be improved by applying a longer screening interval,[29] screening a more restricted population,[30] or considering primary screening for human papilloma virus for some sub-groups.[31]

Implications

The practice nurses in the intervention group proved to be good teachers, but the high intra-cluster correlation coefficient suggests a considerable practitioner effect, with implications for professional training. In addition, there was some evidence that different subsets of women responded differently to the intervention, suggesting the need for an even more individualised approach.[27,28]

The collective risk perceptions of women regarding cervical screening are both inaccurate and amenable to individual interventions. Women's views are also diverse, and therefore unlikely to be evenly altered by a simple population approach. It seems most plausible that we need both population and individual approaches to redress excess testing without causing morbidity. Culture changes in programme delivery are needed,[33] along with education for smear takers, and individual counselling about the advantages and disadvantages of the programme.

This general approach to providing risk information to individuals could have similar effects in other screening programmes, in relieving unnecessary anxiety, increasing autonomy and choice in decisions about screening. On the other hand, risk information in programmes for more common cancers, such as breast cancer, may increase concern and therefore pressure for testing. Further research will be needed on achieving a balance between population and individual perspectives and interventions as screening and risk management programmes proliferate.

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Acknowledgements

This trial was funded by the Welsh Office of Research and Development. The authors would like to extend their gratitude to all the women and their practice teams who participated, to Sister Celia Drew and Sister Linda Whittaker for enthusing and co-ordinating the practice nurses, to Mrs Val Roberts and Mrs Diana Pasterfield for their clerical support, and to the laboratory staff in Wrexham, Chester and Glan Clwyd, in particular Virginia Seager, Linda Lee and Julie Scanlan.