Greta Westwood, Ruth Pickering, Sue Latter, Paul Little, Karen Gerard, Anneke Lucassen and I Karen Temple

A primary care specialist genetics service:

a cluster-randomised factorial trial

Abstract

Background
GPs do not have the confidence to identify patients at increased genetic risk. A specialist primary care clinical genetics service could support GPs with referral and provide local clinics for their patients.

Aim
To test whether primary care genetic-led genetics education improves both non-cancer and cancer referral rates, and primary care-led genetics clinics improve the patient pathway.

Design and setting
Cluster-randomised factorial trial in 73 general practices in the south of England.

Method
Practices randomised to receive case scenario based seminar (intervention) or not (control), and referred patients a primary (intervention) or secondary (control) care genetic counsellor (GC)-led appointment. Outcome measures: GP referral and clinic attendance rates (primary), appropriate cancer and case scenario referral rates, patient satisfaction, clinic costs, and case management (secondary).

Results
Eighty-nine and 68 referrals made by 36 intervention and 37 control practices respectively. There was a trend towards an overall higher referral rate among educated GPs (referral rate ratio [RRR] 1.34, 95% confidence interval [CI] = 0.89 to 2.02; $P = 0.161$), and they made more appropriate cancer referrals (RRR 2.36, 95% CI = 1.07 to 5.24; $P = 0.035$). No indication of difference in clinic attendance rates (odds ratio 0.91, 95% CI = 0.43 to 1.95; $P = 0.802$) or patient satisfaction ($P = 0.189$). Patients spent 49% less travelling (£3.60 versus £6.62; $P<0.001$) and took 33% less time (39.7 versus 57.7 minutes; $P<0.001$) to attend a primary than secondary care appointment; 83% of GC-managed appointments met the 18-week referral to treatment, NHS target.

Conclusion
An integrated primary care genetics service both supports GPs in appropriate cancer referral and provides care in the right place by the right person.

Keywords
appropriate referral; cancer genetic referrals; clinical genetics services; genetic counsellors; GP education; primary care.

INTRODUCTION

UK NHS clinical genetics is a specialist tertiary service with 23 regional centres in the UK. One in 10 patients seen in primary care has a medical condition with a genetic component[1] but not all require referral to clinical genetics services (CGS).[2] A third of referrals are received from GPs but not all GPs make referrals and there is wide variation between those who do, suggesting un-met need.[3] Education to reduce inappropriate referrals where there is no benefit, and to increase appropriate referrals where there is benefit is required.[1,4–11] A report[12] of GP referral management identified that referral guidelines, in combination with other support, had the greatest impact on referral behaviour when compared to referral management centres, triage, peer review and the passive use of guidelines. Genetic referral guidelines are only available for cancer family histories in the UK,[13,14] and their use together with a practice-based educational visit improves appropriate referral.[15] However non-practice-based education attracts poor attendance and hence has little effect on cancer genetic referral rates.[10]

UK clinical genetics services adopt a 'hub (tertiary centre) and spoke (secondary care hospital)' service delivery model. Almost 50% of referrals are autonomously managed by genetic counsellors (GCs),[16] all others are referred for another appointment with a consultant clinical geneticist. GCs are either registered nurses or genetic counselling post-graduates.

The current NHS vision aims to integrate some secondary care services into primary care to provide flexible, responsive and patient-centred care closer to home.[17–19] The pilot study[16] to this trial concluded that primary care GC-led clinics were feasible and acceptable to patients, for both non-cancer and cancer referrals. The aims of this trial were to test whether primary care GC-led genetics education improves both non-cancer and cancer referral rates, whether clinic setting influences attendance rates or affects patient and NHS costs, and whether a referral sub-set is suitable for autonomous GC care delivered close to home within the 18-week NHS referral to treatment (RTT) target.[20]

METHOD

New patients referred to the CGS between 1 June 2003 and 30 November 2004 and registered with general practices in an area covering three primary care trusts (PCTs) constituting a 'spoke' with a single secondary care hospital in the South of England with a population of 572 546 were included in the trial. GP referrals only were

G Westwood, PhD, RGN, RM, senior manager HIOW CLRN; **R Pickering**, PhD, senior lecturer, Academic Unit of Primary Care and Population Sciences, Southampton General Hospital, Southampton. **S Latter**, BSc(Hons), RN, PGDipHV, PhD, head of Organisation & Delivery of Care Research Group Faculty of Health Sciences; **K Gerard**, BA (Hons), MSc, PhD, reader in health economics, University of Southampton, Faculty of Health Sciences, Southampton. **P Little**, MD, MRCP, FRCGP, FMedSci, professor of primary care research, Primary Medical Care, Aldermoor Health Centre, Southampton. **A Lucassen**, MPhil (Oxon), FRCP, professor of clinical genetics; **IK Temple**, MD, FRCP, professor of medical genetics, Wessex Clinical Genetics Service, Academic Unit of Genetic Medicine, Southampton University Hospitals Trust, Southampton.

Address for correspondence
Greta Westwood, University Hospital Southampton NHS Foundation Trust, HIOW CLRN, Tremona Road, Southampton, SO16 6YD.

E-mail: greta.westwood@uhs.nhs.uk

Submitted: 25 July 2011; **Editor's response:** 2 September 2011; **final acceptance:** 1 November 2011.

How this fits in

NHS commissioners are now examining referral management to reduce the growth in new outpatient appointments. GPs should be able to recognise and make appropriate clinical genetics referrals but do not have the confidence to do so. Genetic counsellor-led primary care genetics education increases appropriate referrals of patients at moderate and high cancer genetic risk to specialist clinical genetics services. Genetic counsellor-led primary care genetics clinics provide a one-stop clinic for over 60% of GP referrals, only 38% of non-GP referrals and 80% of all cancer referrals regardless of referrer. All (100%) genetic counsellor managed non-cancer referrals met the 18-week referral to treatment NHS target without the need to attend a hospital appointment.

considered in the education comparison. Urgent referrals; previous clinic attendees; triaged to a specialist clinic; requiring a home visit; or those whose referral was dealt with by telephone or letter were excluded from the clinic location comparison. Ethics approval was granted to access routine referral and appointment data.

Seventy-three practices were randomised in a 2x2 factorial design to one of four groups: 1) education and primary care clinic; 2) education and secondary care clinic; 3) no education and primary care clinic; and 4) no education and secondary care clinic. The allocations were computer generated and stratified by PCT.

Educational intervention

Educational needs and preferences for the mode of delivery and content of the education were elicited from a group of 35 GPs (not in the main trial area). They preferred a practice-based informal seminar detailing CGS referral pathways, electronic referral guidelines and example case scenarios illustrating inheritance patterns, recurrence risks and ethical issues. A seminar was designed to include four case scenarios (cystic fibrosis, Huntington's disease, breast cancer, and a child with dysmorphic features referred for diagnosis); referral access details; and the then local and national cancer family history referral guidelines (breast, breast, and ovarian, ovarian, colorectal, and colorectal with other sites).[13,14] An NHS intranet secure website, with access to cancer referral guidelines and a referral form, was developed. All interventional general practices were approached to arrange a seminar. A seminar summary was sent to GPs in practices declining a seminar at the start of the trial, and to control practices at the end of trial.

Clinic location intervention

Eligible patients were sent trial information and a GC appointment in a location determined by their registered general practice: one of four primary care locations[16] closest to the patient's home address or secondary care, a hospital appointment. Each primary care clinic served a population of approximately 75 000 covering eight to nine general practices with an average list size of 8000. Non-cancer and cancer clinics were held weekly and fortnightly respectively, alternating between primary and secondary care locations. A hospital appointment, standard care, could be requested.

Outcome measures

The primary outcome for the education comparison was GP referral rate, while that for the location comparison was clinic attendance rate. The numbers of non-cancer and cancer referrals; patients offered and attended appointments (from both GP and non-GP referrals); and numbers managed autonomously by GCs within the NHS RTT target, were collated from the CGS clinical database. GP referrals were categorised as case scenario or not. Cancer referrals were categorised into low, moderate, or high additional risk (above population risk) according to published guidelines.[13,14] Low genetic risk referrals were referred back to primary care while those at moderate and high genetic risk were assessed as appropriate. General practice data was obtained from PCT offices.

Patients were sent a questionnaire, including a Genetics Appointment Patient Satisfaction Score (GAPSS)[16] and questions addressing clinic travel and other costs, 2 weeks after attending their appointment and a reminder 2 weeks later. Estimation of travel costs was based on the majority mode of travel (private car) for all patients and was calculated as the return mileage, between their home and clinic, at £0.40 per mile[21] together with car parking costs. Travel time, in minutes, was calculated as the return journey time from home to clinic.

Excess NHS treatment costs to provide the primary care clinics included extra staff travel time, room hire and transportation costs (return mileage between CGS base

and clinic, using AA Route Planner,[22] calculated at £0.40 per mile,[22] and car parking costs). GCs' travel time was costed at £0.30 per minute (Agenda for Change band 8a).[23]

Sample size

Sample size was based on the GP referral rate of 0.2 (per 1000 population/year).[16] Assuming the referral rate would be increased by 50% in the educated group, from the formula (7.9) in Machin *et al*[24] comparing two incident rates, 261 634 were required per group (or 523 268 in total) to achieve 80% power in a 5% two-sided test with 18-months' recruitment. The population in the 73 practices was 572 546, slightly larger than required, making some allowance for any intra-cluster correlation. In the 11-month pilot study,[16] 142 eligible, non-cancelled appointments were made so 232 were expected in the 18-month main trial. It was recognised this was insufficient to detect sizeable changes in attendance rate.

Statistical analysis

All analyses were carried out on an intention-to-treat (ITT) basis irrespective of whether education was given by seminar or post, and according to the clinic location allocated to a patient's general practice. Primary outcomes were obtained from routine data so there were no missing values. Numbers of GP referrals were compared between educated and not-educated practices in a Poisson regression model in Stata (version 10) controlled for PCT, age group, and sex and including clustering by practice. Patient numbers on each practice list in sex and 10-year age bands were included as an exposure variable and referral rate modelled. The referral rate ratio (RRR) for educated versus not-educated groups, is presented with 95% confidence interval (CI). Numbers attending clinic appointments were compared between primary and secondary care in a logistic regression model with denominators being non-cancelled first appointments, controlled for PCT, age group, sex, and non-cancer/cancer referral, including clustering by practice in Stata.[24] The odds ratio of attendance is presented with 95% CI. Rates of GP case scenario and appropriate cancer referrals were compared in similar Poisson models. Mean GAPSS score and patient clinic travel costs were compared in a mixed model in SAS PROC MIXED, controlled for PCT, age group, sex, non-cancer/cancer referral, incorporating clustering by practice. Mean differences for NHS costs were compared between clinic locations using independent *t*-tests. The estimation of costs used 2003 data. Percentages autonomously managed by GCs within 18-week RTT were compared between GP and non-GP, and between non-cancer and cancer referrals using χ^2 tests.

Table 1. GP referral rate by education comparison. Figures are *n* (referral rate per 1000) unless stated otherwise

			Controlled and clustering[a] RRR	
	Educated	**Not-educated**	**RRR (95% CI)**	***P*-value**
Population	284 994	287 552		
Total GP referrals	89 (0.31)	68 (0.23)	1.34 (0.89 to 2.02)	0.161[b]
GP non-cancer referrals	60 (0.21)	53 (0.18)	1.15 (0.72 to 1.84)	0.567[b]
GP cancer referrals	29 (0.10)	15 (0.05)	2.02 (1.01 to 4.03)	0.046[b]
GP case scenario referrals[c]	34 (0.12)	26 (0.09)	1.27 (0.73 to 2.21)	0.038[b]
Breast cancer (%)	13 (52)	7 (27)		
Cystic fibrosis (%)	9 (27)	7 (27)		
Huntington's disease (%)	8 (24)	6 (23)		
? Clinical diagnosis (%)	3 (9)	6 (23)		
GP cancer guideline referrals[d]	25 (0.08)	12 (0.04)	2.17 (1.04 to 4.52)	0.038[b]
Breast cancer (%)	13 (52)	7 (58)		
Colorectal cancer (%)	7 (28)	2 (17)		
Ovarian cancer (%)	3 (12)	1 (8)		
Breast and ovarian cancer (%)	2 (8)	2 (17)		
Appropriate GP cancer guideline referrals[d]	23 (0.08)	10 (0.03)	2.36 (1.07 to 5.24)	0.035[b]
Breast cancer (%)	13 (57)	6 (60)		
Colorectal cancer (%)	6 (17)	2 (20)		
Ovarian cancer (%)	3 (13)	1 (10)		
Breast and ovarian cancer (%)	1 (4)	1 (10)		

Educated/Not-educated = referral rate ratio (RRR). [a]Controlled for age, sex, primary care trust including general practice as a clustering variable. [b]From Poisson regression in Stata. [c]Referrals with diagnoses as presented as case scenarios at general practice seminars. [d]Referrals for cancer diagnoses which met cancer referral guideline criteria.

RESULTS

Seventy-three general practices (303 GPs) were randomised to the trial. A CONSORT flowchart of general practices and patients through the trial is available from the authors. Of 36 practices randomised to receive the intervention 11 declined. One hundred and fifty-seven GP referrals were received (89 from educated and 68 from not educated practices) were included in the comparison of the referral rate. Another 375 referrals were received from non-GP referrers. Of the 532 referrals 221 were excluded; 94 were ineligible and a further 110 were seen by a clinical geneticist and 17 had been allocated to a non-study clinic. Three hundred and eleven GC-led appointments were offered to patients (170 in primary and 141 in secondary care) and included in the comparison of the clinic attendance by location. Seventeen patients cancelled and 39 did not attend an appointment (14%). Baseline characteristics of general practices, GPs, and population by trial arm were all were well balanced.

Table 2. Clinic attendance rate by clinic comparison. Figures are *n* (%) unless stated otherwise

	Primary care	Secondary care	Controlled and clustering[b] AOR AOR (95% CI)	*P*-value[c]
All appointments attended[a]	140 (86) (*n* = 162)	114 (86) (*n* = 132)	0.91 (0.43 to 1.95)	0. 802
Non-cancer appointments attended[a]	103 (85) (*n* = 121)	80 (83) (*n* = 96)	0.77 (0.34 to 1.76)	0.534
Cancer appointments attended[a]	37 (90) (*n* = 41)	32 (94) (*n* = 36)	2.69 (0.45 to 15.94)	0.276

[a]First appointments offered only, non-cancelled. [b]Controlled for age, sex, PCT, and cancer versus not cancer including general practice as a clustering variable. Primary care/secondary care = attendance odds ratio (AOR). [c]Poisson regression in Stata.

Education

Eleven practices that declined the seminar received a postal seminar summary. Eighty-one of 117 GPs (69%), four GP trainees, 14 practice nurses, and four other health professionals attended a seminar in the 25 practices that accepted a seminar.

The total referral (89 from educated and 68 from not-educated practices RRR 1.34; 95% CI = 0.89 to 2.02 *P* = 0.161) and the non-cancer referral rates (RRR 1.15; 95% CI = 0.72 to 1.84 *P* = 0.567) did not differ between groups (Table 1). An early trend of increased referrals from the educated practices (35 compared with 21 in the first 6 months, 29 compared with 19 in the second 6 months) was observed, but in the final 6 months the not-educated practices made as many referrals as the educated practices (25 compared with 28 respectively). Cancer (RRR 2.02; 95% CI = 1.01 to 4.03 *P* = 0.046), case scenario (RRR 1.27; 95% CI = 0.73 to 2.21 *P* = 0.038) and appropriate cancer (RRR 2.36; 95% CI = 1.07 to 5.24 *P* = 0.035) referral rates were higher in the intervention practices. Two cancer referrals from each group were inappropriate and were referred back to primary care. Non-cancer referrals included 44 disparate diagnoses compared to nine cancer diagnoses. The overall attendance rate was 86% and did not differ between the clinic locations (Table 2).

Table 3. Mean patient satisfaction, patient and NHS clinic costs by clinic location comparison. Figures are *n* unless stated otherwise

	Primary care	Secondary care	Primary – Secondary (95% CI)	*P*-value
Patient satisfaction	**(*n* = 91)**	**(*n* = 70)**		
GAPSS score				
Mean (SD)	3.50 (0.33)	3.43 (0.39)	0.08	0.189[a]
Minimum to maximum	2.56 to 4.00	2.05 to 4.00	(–0.04 to 0.19)	
Missing	(*n* = 0)	(*n* = 0)		
Patient costs (per clinic appointment)	**(*n* = 91)**	**(*n* = 70)**		
Travel by car (mileage and car parking)				
Mean (SD)	£3.60 (3.16)	£6.62 (4.69)	–£3.28 (–49%)	<0.001[b,c]
Minimum to maximum	£0.00 to £19.20	£0.00 to £19.50	(–£4.76 to –£1.79)	
Missing	(*n* = 2)	(*n* = 2)		
Travel time (minutes)				
Mean (SD)	39.70 (28.00)	57.70 (34.50)	–19.30 (–33%)	<0.001[b,c]
Minimum to maximum	10 to 180	10 to 180	(–30.70 to –7.90)	
Missing	(*n* = 2)	(*n* = 2)		
NHS costs (per clinic)	**(*n* = 12)**	**(*n* = 12)**		
Transportation cost (mileage and parking)				
Mean (SD)	£18.32 (3.52)	£23.70 (0.00)	–£5.38 (–23%)	<0.001[a]
Minimum to maximum	£12.80 to £21.30	£23.70	(–£7.59 to –£3.16)	
Staff travel cost				
Mean (SD)	£21.00 (2.77)	£20.40 (0.00)	£0.60	0.468[a]
Minimum to maximum	£16.80 to £24.00	£20.40	(–£1.14 to £2.34)	
Capital cost (room hire)				
Mean (SD)	£6.25 (11.30)	£0.00	£6.25	0.082[a]
Minimum to maximum	£0.00 to £25.00		(–£0.93 to £13.43)	
Total clinic cost (transportation, staff capital)				
Mean (SD)	£45.57 (5.45)	£44.10 (0.00)	£1.48	0.369[a]
Minimum to maximum	£42.30 to £54.60	£44.10	(–£1.95 to £4.90)	

[a]Controlled for age, sex, primary care trust (PCT), and cancer versus non cancer. [b]Controlled for age, sex, PCT, and cancer versus non cancer including general practice as a clustering variable. [c]From a mixed regression model in SAS PROC MIXED.

Clinic location

Three patients offered a primary care appointment requested a hospital appointment. Of those who did not attend 40% were paediatric referrals. The GAPSS questionnaire was returned by 69% in both groups (Table 3). Mean total GAPSS was similar in the two groups (3.50 versus. 3.43; 95% CI = –0.04 to 0.19; *P* = 0.189).

Patients spent 49% less on travelling (£3.60 versus £6.62; *P*<0.001) and took 33% less time (39.7 versus 57.7 minutes; *P*<0.001) to attend a primary than secondary care appointment (Table 3). NHS mileage and car parking costs were 23% that is £5.38 less per primary care clinic (*P*<0.001), but staff costs were not significantly different. One host practice charged £25.00 for room hire, contributing to the average incremental capital cost difference of £6.25 (*P* = 0.082) per clinic. Overall no difference in NHS excess treatment costs was identified (£45.57 versus £44.10; *P* = 0.369).

GCs independently managed 48% of all referrals: 62% (*n* = 62) of GP referrals and 38% (*n* = 62) of non-GP referrals (*P*<0.001) (Table 4). More GP cancer referrals were managed entirely by GCs than GP non-cancer referrals (79% versus 56%; *P* = 0.057): among non-GP referrals the same pattern was observed (81% versus 21%; *P*<0.001). There was also a difference between GP and non-GP non-cancer referrals (56% versus 21%; *P*<0.001) and 83% of all GC managed referrals (100% non-cancer and 65% cancer referrals) were managed within the 18-week RTT target.

DISCUSSION

Summary

This trial demonstrated that GC-led primary care genetics education increased GP appropriate referral of patients at moderate

Table 4. Referrals independently managed by genetic counsellors by referrer type and within 18-week referral to treatment NHS target. Figures are *n* (%) unless stated otherwise

	GP referrals[a]	Non-GP referrals[b]	*P*-value	18-week referral to treatment NHS target
Non-cancer referrals	40 (56) (*n* = 72)	24 (21) (*n* = 114)	<0.001[c]	64/64 (100)
Cancer referrals	22 (79) (*n* = 28)	38 (81) (*n* = 47)	1.000[c]	39/60 (65)
P-value	0.057	<0.001		
Total referrals	62 (62) (*n* = 100)	62 (38) (*n* = 161)	<0.001[c]	103/124 (83)

[a]*Includes three reappointments.* [b]*Includes four reappointments.* [c]χ^2 *test.*

and high genetic risk of developing cancer. Appropriate referral was judged against the national guidelines, some now incorporated as NICE guidelines.[13] It remains difficult to improve non-cancer referral patterns due to the lack of guidelines and the heterogeneous non-cancer genetic diagnoses. There was no evidence that clinic location affected attendance rates or overall NHS costs; however it was almost 50% less expensive and 33% less distance for patients to attend primary care compared with hospital clinics. A subset of referrals can be managed autonomously by GCs, of which 100% of non-cancer referrals were managed within the NHS target of 18 weeks: provided in the right place, by the right person giving the right care.

Strengths and limitations

Both interventions were piloted prior to the start of the trial and an evaluation of the primary care location reported elsewhere.[16] The model tested in this trial is generalisable across the UK and other countries operating similar clinical policy and a 'hub and spoke' model of service delivery.

Biases occurring in cluster randomised trials have been identified.[25] There was no bias in the selection of practices or patients to this trial since the primary outcomes were based on routine data, available for all the practices included in the analysis on an ITT basis. Recruitment of patients to the trial was effectively the primary outcome of the education comparison, referral rate. GPs would become aware of the location allocated to their practice, but individual GPs typically referred only one or two patients, so that lack of blinding to location was unlikely to greatly affect referral rates. At the time of the trial the NHS Choose and Book Scheme[26] was unavailable so GPs were unable to refer other than to the regional CGS. Blinding of outcome assessment did not affect the primary analyses; other outcomes were obtained from self-completed questionnaires. Patients would be aware of their clinic location, although probably not of the educated status of their general practice.

This trial aimed to increase overall referrals and to increase appropriate referrals, but not at the expense of an increase of inappropriate referrals (false positives). Cancer referral guidelines enabled this to be checked but this was not possible for non-cancer referrals. A notes review was not undertaken to identify those patients not referred. Genetic referral is now a required component of GP training, included in the Royal College of General Practice (RCGP) curriculum statement, published after this trial closed.[1] However, since the majority of practising GPs qualified before 2007 the impact of the statement may take some years to have its full impact of referral patterns. Although practice-based education increased appropriate cancer referrals in this trial it is recommended that educational effort should be sustained as the increase in referrals was most noticeable in the first 12 months.

It was recognised, at the outset that the sample size would not be adequate to demonstrate anything other than very large changes in clinic attendance rates, and in particular not adequate to demonstrate narrow equivalence limits. Funding for this trial was only available for 3 years, so an extension of the intervention period over a longer period or the inclusion of a greater population base was not possible.

Comparison with existing literature

The primary care-based educational intervention, a stand alone, one-off genetics seminar was systematically developed using GP preferences for content and delivery.[27–30] Seminar attendance was high but a difference in overall referrals might have been identified if more GPs had received the intervention. Face-to-face educational interventions were found to have greater impact on referral patterns than postal educational packs alone or non-practice-based education such as computer software support, as evaluated by Wilson *et al*.[10] There was a trend of increased overall referrals in the first year, but after this both groups had similar referral rates. This supports a recommendation by others;[31] educational inputs should be sustained rather than a one-off effort.

Integrated specialist primary care services have previously been reported as difficult in a review of NHS-funded cancer genetics pilot projects.[32,33] However, this trial has shown them to be achievable for both

Funding

Genetics Policy Unit, Department of Health. Trial registration number ISRCTN68167690.

Ethical approval

Portsmouth and Isle of Wight local ethics committee 07/02/1377.

Provenance

Freely submitted; externally peer reviewed.

Competing interests

The authors have stated that there are none.

Acknowledgements

Janet Shea-Simonds, Lorna Day and Jess Shearn (Genetic Counsellors) provided the clinics.

Discuss this article

Contribute and read comments about this article on the Discussion Forum: **http://www.rcgp.org.uk/bjgp-discuss**

cancer and the more difficult non-cancer referrals. This trial demonstrated that the shift of the provision of services across sector, organisation, and professional boundaries is possible.

The clinic attendance rate was high and improved from the pilot study[16] and may be the reason why no difference was identified between clinic locations. There may be a 'ceiling' for attendance with a residual group not attending wherever a clinic is located. In the systematic review[34] of 26 studies investigating the benefits of outreach primary care clinics, no general conclusion could be made about clinic attendance rates between primary and secondary settings, but attendance appeared to be specialty specific. Patients value local and accessible clinical genetics services, and described challenges faced if more than one family member also attends and the service is provided at a regional centre which may be far away.[35]

Implications for research and practice

As NHS commissioners now examine referral management to reduce the growth in new outpatient appointments, strategies are needed to address the patient pathway for non-GP non-cancer genetic referrals. Unnecessary appointments could be avoided if these referrals are dealt with by a geneticist from the outset. Only a limited range of cost consequences were investigated in the current trial. A fuller cost effectiveness analysis of the intervention from the perspectives of both patient and the NHS including the impact of clinical costs and referral improvements remains to be done.

Based on the results of this study, in collaboration with specialist genetics services and primary care, there is a need to develop a competent practice nurse-led clinical genetics service for a sub-set of all GP referrals and a cluster of eight general practices. This will require the development of non-cancer referral guidelines and patient outcome data to evaluate the appropriateness of the new service but would ensure a subset of well, low genetic risk patients remain in primary care.

REFERENCES

1. Royal College of General Practitioners. *Genetics in primary care*. Curriculum Statement 6. London: RCGP, 2007. http://www .rcgp-curriculum.org.uk/PDF/curr_6_Genetics_in_Primary_Care.pdf (accessed 25 Jan 2012).
2. Watson E, Austoker J, Lucassen A. A study of GP referrals to a family cancer clinic for breast/ovarian cancer. *Fam Pract* 2001; **18(2):** 131–134.
3. Suchard M, Yudkin P, Sinsheimer JS, Fowler GH. General practitioners' views on genetic screening for common diseases. *Br J Gen Pract* 1999; **49(438):** 45–46.
4. Houwink EJ, van Luijk SJ, Henneman L, *et al*. Genetic educational needs and the role of genetics in primary care: a focus group study with multiple perspectives. *BMC Fam Pract* 2011; **12:** 5.
5. Mathers J, Greenfield S, Metcalfe A, *et al*. Family history in primary care: understanding GPs' resistance to clinical genetics — qualitative study. *Br J Gen Pract* 2010; DOI: 10.3399/bjgp10X501868.
6. Farndon PA, Bennett C. Genetics education for health professionals: strategies and outcomes from a national initiative in the United Kingdom. *J Genet Couns* 2008; **17(2):** 161–169.
7. Watson EK, Shickle D, Qureshi N, *et al*. The 'new genetics' and primary care: GPs' views on their role and their educational needs. *Fam Pract* 1999; **16(4):** 420–425.
8. Kumar S, Gantley M. Tensions between policy makers and general practitioners in implementing new genetics: grounded theory interview study. *BMJ* 1999; **319(7222):** 1410–1413.
9. Fry A, Campbell H, Gudmunsdottir H, *et al*. GPs' views on their role in cancer genetics services and current practice. *Fam Pract* 1999; **16(5):** 468–474.
10. Wilson BJ, Torrance N, Mollison J, *et al*. Improving the referral process for familial breast cancer genetic counselling: findings of three randomised controlled trials of two interventions. *Health Technol Assess* 2005; **9(3):** iii–iv; 1–126.
11. Department of Health. *Cancer reform strategy*. London: Department of Health, 2007.
12. Imison C, Naylor C. *Referral management lessons for success*. London: Kings Fund, 2010.
13. National Institute for Health and Clinical Excellence. *Familial breast cancer: The classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care*. Clinical guidelines, CG41. NICE, 2006. http://www.nice.org.uk/guidance/CG41 (accessed 25 Jan 2012).
14. Cairns SR, Scholefield JH, Steele RJ, *et al*. British Society of Gastroenterology; Association of Coloproctology for Great Britain and Ireland. Guidelines for colorectal cancer screening and surveillance in moderate and high risk groups (update from 2002). *Gut* 2010; **59(5):** 666–689.
15. Watson E, Clements A, Lucassen A, *et al*. Education improves general practitioner (GP) management of familial breast/ovarian cancer: findings from a cluster randomised controlled trial. *J Med Genet* 2002; **39(10):** 779–781.
16. Westwood G, Pickering RM, Latter S, *et al*. Feasibility and acceptability of providing nurse counsellor genetics clinics in primary care. *J Adv Nurs* 2006; **53(5):** 591–604.
17. Department of Health. *Equity and excellence: liberating the NHS*. London: Department of Health, 2010.
18. Darzi A. *High quality care for all: NHS Next Stage Review Final Report*. London: TSO, 2008.
19. Department of Health. *Our health, our care, our say: a new direction for community services*. London: Department of Health, 2006.
20. Flory D. GP Referral for Clinical Genetics Services 2008 [letter]. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_090164.pdf (accessed 31 Jan 2012).
21. HM Revenue and Customs. *Travel — mileage and fuel allowances*. http://www.hmrc.gov.uk/rates/travel.htm (accessed 25 Jan 2012).
22. The Automobile Association. *Classic route planner*. http://www.theaa.com/route-planner/classic/planner_main.jsp (accessed 25 Jan 2012).
23. Department of Health. *NHS pay modernisation in England: agenda for change*. London: Department of Health, 2009. http://www.official-documents.gov.uk/document/hc0809/hc01/0125/0125.pdf (accessed 25 Jan 2012).
24. Machin D, Campbell M, Fryers P, Pinol A. *Sample size tables for clinical studies*. 2nd edn. Oxford: Blackwell Science, 1997.
25. Eldridge S, Ashby D, Bennett C, *et al*. Internal and external validity of cluster randomised trials: systematic review of recent trials. *BMJ* 2008; **336(7649):** 876–880.
26. Department of Health. *Choose and book: patient's choice of hospital and booked appointment-policy framework*. London: The Stationery Office, 2004.
27. Julian-Reynier C, Nippert I, Calefato JM, *et al*. Genetics in clinical practice: general practitioners' educational priorities in European countries. *Genet Med* 2008; **10(2):** 107–113.
28. Gaff CL, Aitken M, Flouris A, Metcalfe SA. A model for the development of genetics education programs for health professionals. *Genet Med* 2007; **9(7):** 451–457.
29. Brandt R, Ali Z, Sabel A, *et al*. Cancer genetics evaluation: barriers to and improvements for referral. *Genet Test* 2008; **12(1):** 9–12.
30. Watson E, Clements A, Yudkin P, *et al*. Evaluation of the impact of two educational interventions on GP management of familial breast/ovarian cancer cases: a cluster randomised controlled trial. *Br J Gen Pract* 2001; **51(471):** 817–821.
31. O'Brien MA, Rogers S, Jamtvedt G, *et al*. Educational outreach visits: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev* 2007; **(4):** CD000409.
32. Martin GP, Finn R, Currie G. National evaluation of NHS genetics service investments: emerging issues from the cancer genetics pilots. *Fam Cancer* 2007; **6(2):** 257–263.
33. Bennett C, Burton H, Farndon P. Competences, education and support for new roles in cancer genetics services: outcomes from the cancer genetics pilot projects. *Fam Cancer* 2007; **6(2):** 171–180.
34. Powell J. Systematic review of outreach clinics in primary care in the UK. *J Health Serv Res Policy* 2002; **7(3):** 177–183.
35. McAllister M, Payne K, MacLeod R, *et al*. What process attributes of clinical genetics services could maximise patient benefits? *Eur J Hum Genet* 2008; **16(12):** 1467–1476.