Evaluation of a Primary Care Dermatology Service: final report

Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO)

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Executive Summary

Introduction

The NHS Plan promoted the concept of the general practitioner with special interests (GPSI). There were a number of factors leading to this initiative, in particular the need to increase capacity in the face of rising demand for specialist advice and to reduce excessive waiting lists for hospital outpatient appointments.

Many GPSI schemes have been established by Primary Care Trusts (PCTs) in a number of clinical fields, but there is a lack of evidence about the costs and benefits of these schemes. A GPSI service for dermatology was established in Bristol in 2001, and was subject to rigorous evaluation. Dermatology represents one of the most common causes for consultation in primary care and for referral to secondary care. More GPSIs are operating in dermatology than in any other clinical speciality, other than diabetes.

Setting and intervention

The Bristol Primary Care Dermatology Service (PCDS) is staffed by two GPSIs and a specialist nurse, and is provided from a suburban health centre. It provides care for patients referred by general practitioners in the area served by Bristol South and West PCT. Patients are referred by their general practitioners (GPs) to the outpatient Dermatology Centre at the Bristol Royal Infirmary as usual. Those who appear on the basis of their referral letter to be suitable for management in the PCDS are given an appointment there rather than at the outpatient department. At the time of the trial, suitable patients were adults with non-urgent skin conditions with a provisional diagnosis made by their GP.

Aims and objectives

Aim

The aim of this study was to investigate the effectiveness, cost-effectiveness, accessibility and acceptability of a PCDS in comparison with a hospital outpatient clinic for dermatology.

Research objectives

- To determine the proportion of patients referred by general practitioners with dermatological problems which can be managed in a PCDS rather than a specialist dermatology hospital outpatient clinic.

- To determine whether a PCDS impacts on access to care for patients.
- To compare the effectiveness and cost-effectiveness of providing care in a PCDS or a hospital outpatient clinic. Costs are assessed from a societal perspective with patient costs and NHS costs clearly distinguished.
- To determine patients' satisfaction with care received in the PCDS compared with a hospital outpatient clinic.

Overview of study design

- A randomised controlled trial comparing patients referred to the PCDS with those receiving usual care at the hospital outpatient clinic.
- An economic evaluation providing data about the cost-effectiveness of these alternative models of service provision.
- Analysis of routine data from the study PCT and three neighbouring trusts, providing further information about referral rates and waiting times for appointments.
- A qualitative study exploring issues that were important to patients in relation to improving access to dermatology services.
- A discrete-choice modelling study quantifying patients' preferences for different aspects of access to dermatology services.

Methods and results

Randomised controlled trial

Methods

All adult dermatology referrals from 30 practices in one PCT area over 14 months were triaged according to potential suitability for PCDS, and suitable patients invited to participate. Consenting patients were randomised in a 2:1 ratio to the PCDS or usual outpatient care. Primary outcomes were disease-related quality of life (Dermatology Life Quality Index (DLQI), with higher scores reflecting worse quality of life) and improved patient-perceived access (using a new scale devised for this study, scored out of 100). Secondary outcomes were waiting times, rates of non-attendance (did not attend (DNA) rates), patient satisfaction (Consultation Satisfaction Questionnaire (CSQ), scored out of 100) and patient preference. Outcomes were assessed 9 months after randomisation. Analysis was by intention-to-treat. Process measures included follow-up rates at the PCDS or hospital. Sample-size calculations were based on seeking to establish equivalence between the PCDS and hospital in terms of effectiveness (the DLQI). A sample size of 290 patients in the primary-care arm and 145 patients in the hospital arm would provide 80% power to rule out

differences larger than 0.285 standard deviations in either direction, on the basis of two-sided 95% confidence intervals and assuming no difference between the two groups in terms of (true) effectiveness.

Results

Of all referrals, 49% (987/2028) appeared from the referral letter to be suitable for management in the PCDS. After exclusions, of the 768 patients eligible, 556 (72%) were randomised, 354 to PCDS and 202 to outpatients. After 9 months, 422 (76%) were followed up. Patient characteristics in trial arms were similar at baseline. There were no marked differences between the PCDS and hospital care in respect of clinical outcome (median DLQI was 1 in both arms; ratio of geometric means, 0.99; 95% confidence interval (CI), 0.85–1.15; P=0.9, adjusting for baseline and stratification). The PCDS was more accessible (the difference between means on the access scale (scored out of 100) was 14; 95% CI, 11–19; P<0.001) and patients had reduced waiting times by a mean of 40 days (95% CI, 35–46 days; P<0.001). Patients expressed slightly greater satisfaction with PCDS consultations (difference in mean CSQ, 4%; 95% CI, 1–7%; P=0.011) and were more likely to prefer care at PCDS, both at baseline and after 9 months. Fewer PCDS patients (6%) than hospital patients (11%) failed to attend their initial appointment, but overall DNA rates for new and follow-up appointments were similar in both sites (PCDS, 8%; hospital, 11%). Of those patients seen initially at PCDS, 12% were referred to the hospital for one or more follow-up appointments.

Economic evaluation

Methods

Costs were evaluated from the perspective of the NHS, patients, their families and society for the 9 months following randomisation. Costs identified as being important included: the costs of consultation in secondary and primary-care services; investigations, medication and procedures; travel costs; over-the-counter costs; costs of private treatment; and costs of lost production. Resource-use data were collected from a combination of NHS computerised systems and patient questionnaires, and were valued at 2004 prices using data from the hospital, the PCDS and a variety of national sources. Cost-effectiveness, using the two primary outcomes of the DLQI and improved patient-perceived access, was assessed in terms of incremental cost-effectiveness ratios and cost-effectiveness acceptability curves. Cost-consequences are presented in relation to all costs and both primary and secondary outcomes from the trial. One sensitivity analysis was conducted to estimate the impact of increasing the number of patients seen in the PCDS.

Results

The costs to the NHS of the PCDS were considerably greater than the costs of hospital outpatient care (cost per patient over 9 months: PCDS, £207.91; hospital, £118.13). This was mainly due to the higher costs of doctors' and nurses' time, which were related to the longer consultations at the PCDS, the higher number of consultations received by patients in the PCDS and the higher cost of nurse consultations. The cost to patients of attending the PCDS was less than that of attending the hospital, as was the cost of lost production. This was due to the finding that patients attending the PCDS lost less time from work. Based on analysis with imputation of missing data, costs to patients and companions were £48 at PCDS and £51 at hospital; costs of lost production were £27 at PCDS and £34 at hospital. The incremental cost-effectiveness ratios for PCDS over hospital care were (i) £540 per one-point gain in the DLQI and (ii) £66 per ten-point change in the access scale.

Overall, when NHS, patient and lost production costs were combined, the cost of providing care at the PCDS was greater than the cost of providing hospital outpatient care. This overall finding was not influenced by the sensitivity analysis.

Analysis of waiting times and referral rates

Methods

Routine data about referrals to dermatology outpatient departments from GPs in the study PCT and three neighbouring PCTS were obtained from the Avon Information Management and Technology consortium. Descriptive analysis was conducted, as the small number of trusts and the high level of month-to-month variation made statistical comparison inappropriate.

Results

Before the study began the acute trust that was the focus of this research had lower waiting times than other trusts. Over the period of the study waiting times in neighbouring trusts improved so that mean waiting times converged at about 65 days in all trusts.

Between 2001 and 2004 the number of referrals to dermatology from GPs in the study PCT increased by 22%, compared with smaller increases in the neighbouring PCTs.

The total number of patients transferred from the outpatient department in this study to the PCDS represented just 8% of all referrals received. Therefore it is unlikely that the PCDS would have a major impact on waiting times at the acute trust.

Qualitative study

Methods

Twenty patients suitable for the PCDS but not involved in the randomised controlled trial were interviewed using a semi-structured interview schedule. Exploratory analysis using constant comparison and grounded theory techniques was used. Interviews and analysis proceeded iteratively through a series of rounds.

Results

The acceptability of a local dermatology service was influenced by four inter-related themes: participants' perception of their need (urgency) for diagnosis or treatment, which influenced their willingness to wait for an appointment; their experience of primary-care services; their perception of what constitutes specialist expertise and factors relating to the convenience of the respective services.

Discrete-choice modelling

Methods

The interviews conducted in the qualitative study were also used to identify issues of importance to patients in regard to access to dermatology services and realistic levels for these attributes, in order to inform the design of a questionnaire. Four attributes of 'time waited', 'expertise', 'convenience' and 'individualised care' were included in a questionnaire which asked respondents to choose between 'best' and 'worst' scenarios for care. Individuals were sent questionnaires by post. People were randomly sent long or short versions of the questionnaire to answer a methodological question about the impact of questionnaire design on response rates.

Results

Of 456 suitable patients, 240 agreed to participate. The response rate to the short version (103/121; 85%) was not markedly greater than to the long version (99/119; 83%). The most important attributes to patients appeared to be the thoroughness of the consultation and the expertise of the doctor, with convenience and waiting times being less important.

Discussion and conclusions

The PCDS appeared to provide care which was more accessible and preferred by patients, with no evidence of a difference in clinical outcomes. These benefits were obtained at considerably greater cost. Although patients referred to the PCDS had much shorter waiting times than those seen at the hospital outpatient clinic, there was no overall beneficial impact on waiting times at the outpatient clinic.

The most important benefit to patients from establishing the PCDS appears to be in terms of accessibility. The location of a GPSI service is therefore crucial in order to maximise accessibility and convenience for as many people as possible. A notable finding from the qualitative research is that accessibility is a complex issue which is not simply based on geographical proximity. The discrete-choice modelling study also showed that improvements in access such as waiting times and convenience were less important to patients than the thoroughness of the consultation and the expertise of the doctor.

The benefits identified for the PCDS need to be compared with other ways of increasing service capacity, for example by providing extra resources to support existing hospital services, by managing demand differently within hospitals, or by employing different models of skill-mix in primary-care-based services.

The Report

Section 1 Background

1.1 The importance of dermatology in primary care

Skin diseases affect a third of the population and 15% of the UK population consult annually for advice or treatment. Dermatological conditions were the fourth most common reason for people consulting general practitioners (GPs) in England and Wales in 1991/92 (McCormick et al., 1995) and are one of the commonest reasons for certified incapacity to work in the UK. Demand is likely to increase in view of rising prevalence of common skin diseases such as atopic eczema, venous ulcers and skin cancer, and increasing awareness of treatment possibilities (Williams, 1997).

1.2 Models of care in dermatology services

The traditional service model for dermatology involves the majority of skin diseases being treated in the community, with referral to hospital consultants where necessary. This model is inadequate to meet current and increasing demand, with long waiting times for outpatient appointments being commonly reported.

An 'outreach' model of care has been popular, particularly during the fundholding era, with consultant dermatologists holding clinics in GP surgeries. A number of small-scale evaluations have been published, reporting improved access and patient satisfaction. However, expected benefits in terms of GP communication and education have not been demonstrated; neither has cost-effectiveness, with higher costs reported than traditional outpatients' clinics (Black *et al*., 1997; Bond *et al*., 2000).

A further, hybrid model involves hospital-based dermatology centres with community liaison teams, and a greater role for specialist nurses and community shared-care clinics; such models have also not been evaluated (Williams, 1997).

More recently, services delivered by general practitioners with special interests (GPSIs) have been the focus of much attention. Dermatology is one of the clinical areas proposed in the NHS Plan and elsewhere as particularly appropriate for development of GPSIs in view of the significant access problems within this speciality (Royal College of General Practitioners, Department of Health, 2002). A national programme has been established, with a number of pilot sites looking at new ways of working including GPSI services (Department of Health, 2003a).

1.3 GPSIs

Models of care incorporating enhanced roles for specialist GPs and nurses working in close liaison with secondary-care colleagues to provide services for patients outside their own practice are being developed across a variety of clinical areas. These areas include (but are not limited to) dermatology, care of older people, mental health, sexual health, diabetes, epilepsy, ear, nose and throat, rheumatology, palliative care and drug misuse (Jones and Bartholomew, 2002; Birch, 2004). Such roles were promoted in the NHS Plan (Department of Health, 2000), which set a target for the introduction of 1000 GPSIs by 2004, although by 2003 this had already been exceeded (Department of Health, 2005a). The development of GPSI services is part of a broader trend towards providing a wider range and volume of services in primary care and blurring of boundaries between primary and secondary care.

The concept of GPs working in clinical specialties is not new: in a recent survey of UK GPs, over 70% of responders had at least one area of clinical interest, the commonest being diabetes, followed by dermatology (Jones and Bartholomew, 2002). An estimated 16% of UK GPs were undertaking clinical sessions in areas of interest, many as clinical assistants, hospital practitioners or practice leads in defined clinical areas.

GPSIs have been defined as general practitioners who supplement their generalist role by delivering high-quality, improved-access services to meet the needs of a Primary Care Trust (PCT) or group of PCTs. Clinical services provided are beyond the normal scope of general practice but are not equivalent to a full consultant service and do not interfere with access to consultants by local GPs. Whereas GPSI services will not be equivalent in breadth to a consultant service, within their role definition they should offer care with as high a quality of process and outcomes as the equivalent services in other settings (Royal College of General Practitioners, Department of Health, 2002).

It is important to recognise that there are several models of organisation of GPSI services. In some cases, referrals are made in the usual way to the hospital clinic, but suitable cases are transferred to the GPSI. This decision may be made by the consultant or the GPSI choosing patients they wish to take. In other models, GPs can refer directly to the GPSI instead of referring to the consultant at the hospital, and this latter model is probably more common. Decisions about where to refer are often informed by referral guidelines (Department of Health, 2003a).

There may also be differences in the range of problems that the GPSIs deal with (Nocon and Leese, 2004). For example, in relation to dermatology, three models have been proposed (British Association of Dermatologists, 2002). GPSIs may run general dermatology clinics in the community, but with strong links to the local dermatology department. Secondly, GPSI services may provide care for a limited

range of conditions such as eczema, psoriasis and/or leg ulcers. Thirdly, GPSIs may just provide skin-surgery sessions (British Association of Dermatologists, 2002).

GPSIs not only provide direct clinical care for individual patients. They can have a role in educating other local practitioners, providing leadership, representing their peers in service development and taking part in quality assurance, research, public health and management (Royal College of General Practitioners, 2004).

The introduction of GPSIs was quickly followed by the promotion of the concept of Practitioners with Special Interests (Department of Health, 2005a). Bringing GPSIs under this broader term reflected the fact that as well as GPs being encouraged to develop specialist roles, the same also applied to other practitioners such as nurses (Department of Health, 2003b) and allied health professionals. In the context of dermatology, this is particularly relevant to the role of specialist nurses. In some community dermatology clinics, GPSIs and nurses with special interests work together. But in other models specialist nurses take the lead role, without any involvement from doctors (Department of Health, 2003a).

1.4 Potential benefits and risks of GPSI services

The policy reasons for encouraging the development of GPSIs can be summarised as follows (Nocon and Leese, 2004):

- to reduce waiting times for treatment;
- to meet needs in primary rather than secondary care;
- to enhance the quality of primary-care services;
- to enable secondary care to concentrate its efforts and resources where its skills are needed most;
- to improve career opportunities for GPs;
- to reduce costs.

1.4.1 Reducing waiting times

Achieving a reduction in waiting times is a key factor behind the policy of promoting GPSIs, linked to the NHS Plan's commitment to reduce the maximum wait for outpatients to 3 months by the end of 2005. This is only likely to be achieved by a considerable expansion in the capacity of the service, and one way to achieve this is through utilising the expertise of GPs with extra training in a speciality, albeit with a lower level of expertise than that of consultants.

Within dermatology, the long-term upward trend in outpatient attendances and long waiting times for specialist opinion have focused attention on new ways of dealing with the demand. At present there is only one consultant dermatologist per 150 000 of the population and the potential for more dermatological care to be managed in the

community is significant. One study has reported that about 20% of referrals to consultant dermatologists could have been managed in primary care without the need for specialist facilities or treatment (Basarab *et al.*, 1996). The idea of a greater role for GPs and nurse specialists was supported by the findings of a dermatology care working group (Dermatological Care Working Group, 2001).

1.4.2 Meeting needs in primary rather than secondary care

The development of GPSI services aims to deliver improved access to care, both through more convenient care closer to peoples' homes and faster access to care than hospital outpatients. This may also lead to a reduction in non-attendance rates.

Because GPSIs are not restricted to working in hospital settings, they may operate in a variety of locations close to where people live, such as GP surgeries, community hospitals or NHS walk-in centres (Department of Health, 2005a). Providing more local services may also improve equity in the availability of care (British Association of Dermatologists, 2002).

Enhancing quality

Optimised primary-care management of skin problems may represent an opportunity to enhance holistic patient care (Ruane-Morris *et al*., 1995). For chronic inflammatory conditions, effective treatment depends a great deal on patient understanding and self-management (Charman, 2000) and patients have expressed a desire for increased educational input. Guidelines, supported by evidence, are available for structured, protocol-driven specialist nursing care. Dermatological conditions are associated with considerable social disability and psychological morbidity (Jowett and Ryan, 1985; Ginsburg *et al*., 1993; Hahiro and Okumara, 1997; Lewis-Jones, 1999; Mallon *et al*., 1999; Harlow *et al*., 2000). Psychosocial support and the services of the various members of the primary health care team (social workers, counsellors and health visitors, with links to local schools and benefits advice) and local support groups could be accessed more readily in a primary-care setting.

Encouraging GPs to acquire specialist skills may have knock-on benefits in raising the quality of care more generally. They will be able to have an educational role with their peers, and be more accessible to provide informal advice to other GPs. In this way it is envisaged that the expertise of GPSIs will spread to their colleagues.

PCDSs involving an enhanced role for nurses are consistent with the increasing importance of specialist liaison nurses in providing a bridge between primary and secondary care in a range of diseases, including diabetes, renal disease, heart disease and asthma, as well as dermatology.

Concentrating the efforts of secondary care

As well as increasing capacity and providing patients with faster access to care, the diversion of a considerable proportion of the more minor cases could reduce waiting times for consultant-led specialist care in hospitals. This would allow hospital staff to concentrate on more complex cases, making best use of their skills (Department of Health, 2005a).

Improving career opportunities for GPs

New GPSI roles may also support GP professional development, and may help to address current difficulties in recruiting and retaining GPs (Royal College of General Practitioners, Department of Health, 2002). Recruitment of GPs is difficult in some parts of the country, and some areas (notably Bradford) have used the establishment of a wide range of GPSI schemes as a strategy to attract and retain doctors to provide generalist primary care as well as specialist care (Rosen *et al*., 2005).

Reducing costs

One justification for the introduction of GPSI schemes may be to reduce costs. Although many PCTs may hope to reduce the costs associated with outpatient referrals by introducing GPSI schemes, there is no good reason to assume that these are likely to be less costly than outpatient care per case, and in addition the introduction of a more accessible local service may increase demand.

Guidance

Extensive guidance on GPSIs and Practitioners with Special Interests, both from the Department of Health and professional bodies such as the Royal College of General Practitioners, is now available, including advice on setting up GPSI schemes, competencies, clinical governance and evaluation (Royal College of General Practitioners, Department of Health, 2002; National Primary Care Trust Development Programme, 2003). Specific frameworks are available for some clinical areas, including dermatology (Royal College of General Practitioners, Department of Health, 2003). Guidance also considers the appropriate local context for GPSI services, as part of a strategy addressing local priorities, with support from all parties along the patient pathway (National Primary Care Trust Development Programme, 2003; Audit Commission, 2004).

Risks

The above guidance reflects a concern that new GPSI services should meet minimum quality standards, and that inexperienced doctors should not be put in the position of making diagnostic or treatment decisions beyond their realm of competence. It is important that all stakeholders are involved at all stages in developing the service and that the GPSIs work closely with the consultant dermatology service (Royal College of General Practitioners, Department of Health, 2003).

However it cannot be assumed that all of the new GPSI services do conform fully to the standards of training and organisation recommended by the various guidance documents (Rosen *et al*., 2005). Although the introduction of this new type of service represents an opportunity for both patients and practitioners, it also carries risks. It is important that these risks are assessed and managed (Birch, 2004).

As well as risks to patients there are also risks to the health system. Concerns have been expressed that the growth in the number of GPSIs may undermine the valuing of generalism (one of the core values on which primary care is based), reduce capacity in general practice and provide a second-class service compared with consultant-led care in hospital (Royal College of General Practitioners, 2004). It cannot be assumed that all innovations which sound attractive are necessarily beneficial, and some changes may have unanticipated adverse effects. It is important to conduct rigorous evaluation, which will involve spelling out the intended benefits of the new scheme and assessing whether these benefits are achieved.

1.5 Evidence for new models of care including GPSIs

A recent evaluation of GPSIs in ear, nose and throat suggested that 30–40% of secondary-care referrals could be managed by primary-care GPSI services given appropriate training and equipment. Rates of patients failing to attend appointments (did not attend (DNA) rates) were around 1–2% in the GPSI clinics (Sanderson, 2002).

Reduced waiting times for secondary care have been reported following the introduction of an early access programme for musculoskeletal problems. Whereas this included the development of GPSI and extended-scope physiotherapy services, integration of hospital departments providing musculoskeletal services and central triage was seen as a key factor leading to improved access. Referral rates doubled, reflecting previously unmet demand, and patient satisfaction with the community clinics was high (Maddison *et al*., 2004).

Studies of a primary-care-based nurse specialist in epilepsy have demonstrated that the service was used by those with greatest needs for care with resulting improvements in communication and treatment compliance, but no change in health status or perceived quality of life (Mills *et al.*, 1999a, 1999b).

The national Dermatological Care Working Group collated evidence from various primary-care dermatology clinic developments: some reductions in secondary-care dermatology waiting lists were reported but only a minority of schemes had evaluated patient outcomes and no conclusions could be drawn (Dermatological Care Working Group, 2001). Overall, the group concluded that such clinics appear to be effective, but that further evaluation is needed.

More recent evidence is becoming available from pilot sites aiming to improve access and quality of care in dermatology, many of which have established GPSIs and other Practitioners with Special Interests as part of service developments (Department of Health, 2003a). Models incorporated varying referral pathways, some directly to GPSIs, others sending selected hospital referrals to GPSIs or using GPSIs to triage referrals. This experience has highlighted the need for strong support from and access to specialist services, and acknowledgement of the workload implications for consultant staff.

Pilot sites generally reported reduced waiting times for secondary care, although they acknowledged the likely effect of other factors such as waiting-list initiatives. Trends in demand were mixed, with reports of both no change in referral thresholds and of rising demand for secondary care. Whether such GPSI services are reducing the need for patients to be referred to secondary care or providing an additional service for new, previously unmet demand is unclear. Reports also suggested positive impacts on staff retention and development, and high levels of patient satisfaction with a GPSI service.

The principle of ensuring that GPSI services have processes and outcomes which are of as high quality as the equivalent services in other settings is explicit in national guidance. This is supported by frameworks of core competencies, training, accreditation, continuing professional development and guidelines for GPSI service use (Royal College of General Practitioners, Department of Health, 2002, 2003). However, robust evidence is not yet available on the important questions of clinical outcomes, including comparisons of outcomes achieved by GPSIs and secondary-care specialists for comparable patients, and cost-effectiveness of GPSI services (Kernick, 2003; Rosen *et al*., 2003; Nocon and Leese, 2004).

1.6 GPSI services in relation to current health policy

The interest in GPSI schemes is consistent with a number of more general themes in current health policy (Department of Health, 2005b). These themes include the following.

- The importance of modernising the NHS to ensure a patient-led service (Department of Health, 2000, 2005c). This includes placing much greater emphasis on patient choice and convenience (Department of Health, 2000, 2003c; nhsalliance, 2004).
- The need to improve access to care (especially by reducing waiting lists; Department of Health, 2000).
- Moving power to PCTs as the commissioning body (Department of Health, 2005d), with a responsibility to develop new services (Department of Health, 2005c).
- Encouraging a multiplicity of providers, with contestability as money follows patients (Ham, 1996; Department of Health, 2002a, 2005c, 2005d).

- The move towards a more flexible workforce not constrained by conventional job titles (Department of Health, 2005a).
- Co-ordination of care for chronic disease across the primary-care/secondary-care interface (Department of Health, 2004a).
- shifting work from secondary to primary care (Department of Health, 2005b).

1.6.1 A patient-led NHS, improving access and choice

The most important aim, and one which underpins the other aims, is to ensure a patient-led NHS. This means designing systems of care which to meet the needs of patients rather than providers, are convenient for patients to use, and are sufficiently flexible to cope with the lifestyles of different patient groups. It also means that everything is measured by its impact on patients (Department of Health, 2005c).

In line with the priority given to improving access to care (both in primary care and in waiting for secondary care following referral) the NHS has been learning from management practices in industrial settings, particularly in relation to process mapping and queuing theory. This has led to identifying and tackling bottlenecks in the system, matching supply to demand and addressing negative assumptions about the inevitability of delays in the system. Within dermatology, it is clear that a shortage of consultants is a bottleneck, with many posts being unfilled. This situation cannot be reversed very quickly; therefore GPSIs provide a quicker means of increasing capacity, particularly in parts of the country that experience difficulty in recruiting consultants (Department of Health, 2003a).

One essential component of the patient-led NHS agenda is the theme of increasing patient choice (nhsalliance, 2004). Providing GPSI services locally may offer patients an alternative to outpatient hospital care. Some people may be willing to see a GPSI for relatively minor problems, especially if they can be seen more quickly, whereas others may prefer to wait longer to see a consultant in a hospital.

1.6.2 Empowering PCTs

The NHS Plan led to a programme of work designed to empower PCTs and give them a central role in running the NHS (Nocon and Leese, 2004; Department of Health, 2005c). This organisational decentralisation was intended to encourage new types of care provision, often in the community rather than in hospitals, based on enhancing the roles of front-line staff (Department of Health, 2005b). This is closely linked to the expansion of physical capacity in primary care with the creation of NHS walk-in centres, diagnostic and treatment centres and enhanced GP practices using the LIFT scheme (Department of Health, 2005b).

The choice and convenience agenda, along with the drive for innovation at the primary-care/secondary-care interface, has led to a willingness to experiment with new ways of providing care to patients, particularly the use of new technologies. For example, within dermatology, nurses with special interests have established telephone advice lines in some areas (Department of Health, 2003a). There has also been interest in the use of tele-dermatology to allow the transmission of photographs of skin lesions to facilitate communication between community clinics and hospital-based specialists (Currell *et al.*, 2000; Eedy and Wootton, 2001; Collins *et al.*, 2004; Lawton *et al.*, 2004).

1.6.3 Multiplicity of providers and contestability

By providing a multiplicity of providers of different types, promoting patient choice and creating payment mechanisms that ensure that money follows patients, the Government hopes to improve quality and value for money. The growth of GPSI services can be seen as one of the range of new providers that is being established under this policy.

1.6.4 Changing workforce

The development of GPSIs illustrates the willingness of policy-makers to question traditional demarcations between professional groups, such as primary- and secondary-care practitioners. This is based on the supposition that much of the work of secondary-care specialists can be done by GPs with much less specialist training or experience. The same trend can be seen in the growth of nursing and allied health professionals with special interests, who are increasingly undertaking roles that were conducted previously by doctors. More generally the same theme is evident in the growth of nurse practitioners, who may substitute for doctors in both primary and secondary care (Horrocks *et al.*, 2002; Laurant *et al.*, 2005).

Nurses and allied health professionals are now organising and running services, particularly in relation to the management of chronic disease, but also in relation to acute minor illness. This is being facilitated by the expansion of their rights to prescribe (Department of Health, 2004b). Although nurses have always had an important role in chronic disease management, the emphasis is increasingly on them working autonomously and taking clinical leadership (Department of Health, 2003b, 2005e). These nurses are often trained to a very high level of expertise within a defined area, work to clear protocols and bring a holistic nursing perspective to the patients' problems. As nurses take on these roles, they may provide a different type of care, hopefully leading to benefits for patients, but also freeing up the time of consultants and GPs to spend with less well defined or more complex cases.

As barriers between professional groups are broken down, there is also increasing emphasis on working in teams, and on working across

the interface between primary and secondary care. This is illustrated in the concept of GPSIs by the need for consultants to be fully involved with establishing the new service. In this way it is intended that the GPSI service will integrate with and support the consultant service, rather than compete with it (Department of Health, 2003a). However given the long-standing rivalries between primary and secondary care, and between doctors and nurses, it is important to study carefully the extent to which this idealised situation is actually achieved.

1.6.5 Improving chronic-disease management

The increasing awareness of the need for better co-ordination of care for patients with chronic disease is also relevant (Department of Health, 2004a). Chronic-disease-management programmes require better integration of generalist and specialist services, with the aim of supporting patients in their efforts to manage their own disease. This usually involves providing care in the most local and least intensive setting possible. It also involves the redesign of services to produce a more effective and efficient use of health professionals' time (Department of Health, 2004a).

1.6.6 Moving services from secondary to primary care

The programme of work building on the NHS Plan included the intention that at least 1 million more outpatients' appointments would take place in the community rather than in hospital (Department of Health, 2002b, 2005b). This will be achieved by developing the roles of primary-care professionals and expanding primary-care facilities. The introduction of practitioners with special interests is an important component of this plan (Department of Health, 2005a, 2005b).

1.7 Summary

Various models of augmented dermatology services in primary care involving specialist roles for GPs and nurses are developing, as are similar services across a range of specialties in response to pressures on secondary care and current national policy. Benefits from such service developments have been reported, but there is a need to ensure that the quality of the service, particularly in terms of clinical outcome, is at least as good as with traditional secondary care, and to understand the relative costs of the models of care. A number of small-scale local evaluations have been conducted, but these have not been sufficiently rigorous to provide good evidence of the effectiveness, cost-effectiveness, accessibility or acceptability of PCDSs based on GPSIs.

Section 2 The Primary Care Dermatology Service and the local context

2.1 The aim of the Primary Care Dermatology Service

In South Bristol, a Primary Care Dermatology Service (PCDS) was established in 2002 as the first local example of a primary-care-based specialist service, in line with the aims of the NHS Plan.

The aims of the service were to:

- improve skills and expertise in managing skin disease in primary care to improve patient care, and where possible to reduce the need for patients to be referred to secondary care;
- by providing services in primary care, to provide quicker, local and more convenient treatment;
- to improve the quality of secondary care by selecting cases with more complex skin disease or treatment requirements to be seen using the specialist staff and facilities in secondary care.

Prior to the establishment of PCDS, general practitioners in South Bristol referred patients with skin problems to the dermatology service at the Bristol Royal Infirmary (BRI). Any benefits of the PCDS in terms of reduced waiting times and more appropriate patients being seen in secondary care would therefore occur at the BRI.

2.2 Rationale for the new service

In the Bristol area, there had been a steady increase in referrals from primary care. Prior to development of the PCDS, waiting times to see a consultant were excessive. In a survey of GPs on priorities for service development in primary care, there was strong support for a primary-care-based dermatology service. This idea was also supported by consultants at the Dermatology Service at the BRI. There had been positive experience nearby in East Bristol and in Somerset of specialist nurses providing dermatology services in the community.

2.3 Description of the service

2.3.1 Location and accessibility

The PCDS is based at the Knowle West Health Park, providing a service to all general practices (n=29) relating to Bristol South and West Primary Care Trust. The health park was established to pioneer innovative ways of delivering health care to the residents of South Bristol. It consists of a number of new services including an NHS walk-in centre, an out-of-hours primary-care centre, a Healthy Living Centre funded by the New Opportunities Fund and a renal dialysis

centre, as well as a large new health centre, which houses two general practices, a pharmacy and a full range of other primary-care professionals. The health centre facilities include a so-called visiting consultants' suite, consisting of two consulting rooms and a small waiting room next to the treatment room and minor operations room. This provided an ideal facility for the PCDS.

Knowle West Health Park attracted this level of investment because it is in a priority area for regeneration. Knowle West is one of the most deprived council estates in the south west of England. This has implications for the perceived accessibility of the PCDS for people who live in South Bristol. Knowle West has a poor reputation with some people in Bristol, many of whom will never have had reason to visit the estate and some of whom may be reluctant to do so because of fears about crime, personal safety or vandalism to their cars.

Although the estate is reasonably well served by buses from the centre of Bristol, it is less easy to reach by public transport from other areas of South Bristol. It is important to note that the area covered by Bristol South and West PCT includes several parts of central Bristol. Many of the patients offered an appointment at PCDS live much closer to the hospital in the city centre than to Knowle West, and for some people (including some who live geographically closer to the PCDS) it is easier to travel by public transport to the hospital in the city centre than to a health centre in a suburban housing estate.

Knowle West Health Park is easy to reach by car, and has a large, free car park.

2.3.2 Referrals to the service

Initially, the service focused on patients who would normally be referred to the outpatient dermatology service. It was decided that GPs would not be allowed direct access to the PCDS, but that GPs should make their referrals as usual to the consultant-led dermatology clinic. The consultant and/or one of the GPSIs reviewed referral letters to identify patients who were suitable for the primary-care service, and these patients were invited to be seen there instead of at the outpatients' department. These triage decisions were initially made by the consultant and a GPSI working together, but as experience was gained these decisions were sometimes made by one of these doctors working alone.

This decision was reached partly because of concerns about inducing demand through direct referral, partly because the service could become fully operational without waiting for GPs to change their referral habits, and partly to facilitate evaluation which was based on a comparison of patients managed in secondary care or in the PCDS. If direct referral led to different types of patients being referred to the PCDS then this type of evaluation would become impossible.

2.3.3 Suitability criteria of patients

The inclusion criteria for suitability for referral to the PCDS were patients of any age with a condition considered suitable by the consultant dermatologist or the specialist GP for management in the primary-care clinic. This particularly included:

- acute and chronic rashes or infective conditions within an established disease category;
- leg ulcers and chronic wounds;
- patients requesting a specialist or second opinion on established diagnoses;
- benign skin lesions causing 'significant handicap' and hence warranting skin surgery according to local guidelines for referral of benign lesions.

Exclusion criteria were:

- conditions or single lesions with no provisional diagnosis by the GP;
- referrals marked urgent by the referring GP or the consultant;
- possible malignancy (2-week cancer-wait patients, dysplastic naevi/melanoma, invasive squamous cell carcinoma or basal cell carcinoma on face or ears);
- patients re-referred after recent discharge from BRI dermatology clinic;
- lesions in the male perineum (because of female staff at service with no chaperone);
- referrals within secondary care;
- referral for assessment for treatment with isotretinoin;
- request for inpatient management;
- where referral was aimed to elicit specific expertise of a named consultant;
- where the referrer was not happy for the patient to be seen by the PCDS.

2.3.4 Staffing

Staff employed to run the service included two GPSIs, a specialist nurse and part-time administrative support. Receptionist cover was bought in from one of the general practices in the health centre in which the PCDS is based. The PCT used its own resources to manage the service and to conduct service monitoring. The consultant dermatologist at the hospital oversaw the development of the service, the training and supervision of the GPSI and specialist nurse, and took overall responsibility for triage of the suitability of patients to be seen at the PCDS.

2.3.5 GPSI sessions

Two GPSIs each provided two sessions a week (four sessions in total) and potentially up to 10 patients per session were seen, with a mixture of new patients and follow-up appointments, giving approximately 40 GP appointments per week in total. From these sessions, two per month were used for minor surgery (about five slots per session, depending on the procedure), providing potentially 10 minor procedures per month. One session of GPSI time every 4–6 weeks was spent for education/triage with the consultant, at either the BRI or PCDS.

2.3.6 Training and experience of the GPSIs

Both of the GPSIs had previously been Clinical Assistants in dermatology for 2 years. One GPSI had a Diploma in Practical Dermatology from Cardiff University at the time of appointment, had been involved in postgraduate dermatology education as an examiner on the Cardiff Diploma and had organised local GP meetings on dermatology. The other GPSI attended the British Society for Dermatological Surgery course in 2001 and obtained the Diploma in Practical Dermatology from Cardiff in 2003. She had previously worked as an senior house officer in dermatology for 6 months as part of a general medical rotation.

2.3.7 Specialist nurse

A specialist nurse was employed full time at the PCDS. Her role was 70% clinical and 30% educational. She held nurse-led clinics, carried out domiciliary visits, provided follow-up to GPSI patients and assisted with GPSI surgery. She provided six clinics per week but urgent patients were seen outside clinic times when necessary. Long appointments were made available for patient education – for example, for teaching wet wrapping – when necessary. The nurse particularly managed the care of adults with inflammatory disease and children with atopic dermatitis. She also had experience and expertise in conditions affecting tissue viability including leg-ulcer management, chronic wound management and 'hard-to-heal' wounds. The specialist nurse had worked within the field of dermatology for the past 13 years. Her previous roles included being ward manager and senior dermatology nurse within secondary care.

2.3.8 Services provided at the PCDS

The PCDS provided several services usually provided by the hospital. These included:

- diagnosis and management of chronic skin conditions and other dermatitis;
- assessing and treating leg ulcers and wounds;
- minor skin surgery;

- cryotherapy and other procedures such as injection of corticosteroids;
- advice, information and education on skin conditions.

Day treatments were not provided due to lack of space, facilities and staff. Neither was phototherapy, iontophoresis or patch testing; therefore, patients who required these services were referred to the hospital for treatment or investigations and then continued visiting the PCDS. There may be scope to expand the service to provide more treatments in future subject to the availability of space and staff. Some appointments outside office hours are offered.

Although not one of the pilot sites in the Action on Dermatology programme, the establishment of the PCDS followed very similar principles to those described at these pilot sites (Department of Health, 2003a).

2.3.9 Differences between the service provided in the PCDS and at hospital

The service provided at the PCDS varied from that provided in the hospital outpatient clinic by being in a smaller, low-tech primary-care environment, which may be more acceptable to some patients. The appointments offered were longer than in hospital. The first consultation was allocated 20 minutes; follow-up consultations were allocated 10 minutes. Minor surgical slots were 20 minutes each but were doubled or tripled as necessary depending on the required surgery.

Nurse slots were 1 hour for first appointments with 30 minutes for follow-up appointments. If patients were referred from a GPSI to the nurse for follow-up they were allocated 30 minutes.

Because the number of staff involved was much smaller, patients at the PCDS were more likely to experience continuity of care from one professional, and there was a stronger emphasis on patient education and nurse management. On the other hand, the range of facilities available in the PCDS was more limited than in the hospital and the GPSIs did not have the same instant access to more expert advice from a consultant that is available to medical staff working in an outpatients' department.

2.3.10 Funding

The budget for the PCDS was £88 244 in 2003–4. Expenditure in this financial year was made up of the elements shown in Table 1.

Set-up costs in 2001 were approximately £31 000, mainly spent on computer systems and equipment for clinical procedures.

The PCDS is funded 50:50 between the PCT and the hospital trust. The figures are reviewed annually.

Table 1 Budget for PCDS in 2003–4

Item	Cost
GPSI salaries	£38 823
Nurse salaries	£32 957
Administrative salaries	£6832
Receptionist cover	£3840
Laboratory results	£760
Insurance	£101
Equipment and computer support	£4931
Total	£88 244

2.4 Outpatient services at BRI

Before the establishment of the PCDS, patients from Bristol South and West (and many from North Bristol and other areas) were referred to the Bristol Dermatology Centre at the BRI. The BRI is a university teaching hospital serving a mixed urban and rural community of about 600 000 people. The complement of five consultants, four specialist registrars and clinical assistants achieves a ratio of about one member of staff for 150 000 population, similar to the national average. The dermatology department provides the full complement of the core dermatology services found in UK dermatology.

The Dermatology Centre is a purpose-built unit with good, modern facilities. Although it is on the main hospital site, it was built after the main hospital and is a separate building with its own entrance.

The BRI is very close to the main Broadmead shopping area in the centre of Bristol, and is also close to the main commercial centre and the University of Bristol. It is easy to reach by public transport, but there is very limited availability of parking nearby, consisting of a few parking meters and a number of expensive multi-story car parks. None of these are very close, making access to the BRI particularly difficult for the elderly or disabled. The Dermatology Centre is behind the main BRI building.

2.5 The local context

2.5.1 Population

Bristol is divided into two PCT areas, one covering the north and the other the south and west. Bristol South and West PCT covers a resident population of about 170 000 people according to the 2001 census. In March 2003 there were 206 496 people registered with GP practices in the PCT. This higher figure includes people who live outside the PCT boundary, and also probably includes an element of

list inflation because people have moved but not yet been de-registered.

The 2001 census showed that 5.2% of the population resident in the PCT area were from black and minority ethnic groups. This is lower than the average for England, which has a non-white population of 9.1%.

The population structure of Bristol is similar to that of England, with the exception of a higher number of young adults aged 20–30, resulting largely from the student population of the two universities (University of Bristol and University of the West of England).

Bristol South and West PCT serves communities with diverse health needs and distinct social circumstances. For example, West Bristol includes Clifton and Redland, both affluent areas with a large population of students and young professionals. It also includes Bristol city centre, which has a mixed population including some commuters, and Hotwells, which is a less affluent area. Bristol South has a high proportion of local authority housing, particularly in Hartcliffe, Withywood and Knowle West. These areas have significant unemployment, and score highly on indicators of deprivation. South-east Bristol includes Brislington, Stockwood, Whitchurch and Hengrove, with a majority of people living in privately owned housing.

Figure 1 shows a map of the area served by Bristol South and West PCT and also the locations of the PCDS and the BRI.

2.5.2 Health services

It is important to recognise that health services in Bristol were operating and continue to operate against a background of substantial financial difficulties. Both of the PCTs in Bristol inherited very large deficits, with North Bristol PCT continuing to have the largest deficit of any PCT in the country. Bristol South and West PCT inherited a deficit of £10 million in April 2002, and has needed to pursue a stringent programme of savings as well as obtaining special financial assistance from the NHS Bank. United Bristol Healthcare Trust, the secondary-care trust which runs the BRI, also had substantial problems. Although the standard of clinical care at this major teaching hospital was recognised to be good, at the time the PCDS was established in 2002 the trust had received a no-star rating in the Commission for Health Improvement annual report. United Bristol Healthcare Trust had incurred a cumulative deficit of £17.34 million and had agreed a recovery plan with the strategic health authority over a 5-year period. Therefore there were considerable pressures on both primary- and secondary-care trusts to maximise the efficiency of the service and also to improve performance in terms of waiting times.

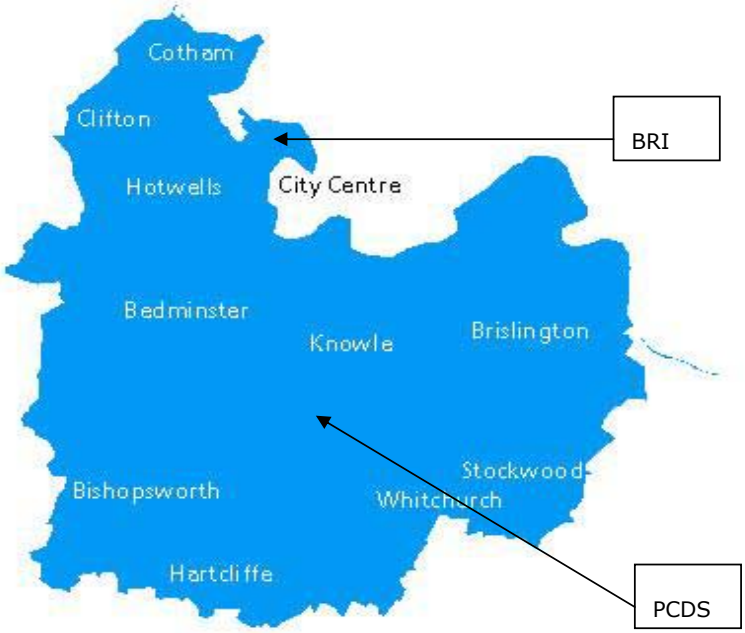


Figure 1 Map of Bristol, showing locations of PCDS and BRI

It is against this background that the PCT and the secondary-care trust were keen to expand capacity using the GPSI initiative in order to reduce waiting-list pressures, as well as to provide a more accessible service to patients.

With regard to this research it is relevant that the above problems at the BRI led to low staff morale at times and difficulties with recruitment and retention. There was a considerable turnover of staff at the BRI dermatology department during the time the PCDS was being established. This provided a challenging environment in which to conduct research, as it was important that all relevant staff fully understood and complied with procedures for the recruitment of patients to the study and the administration of questionnaires.

The physical health care facilities in Bristol are generally in poor condition, reflecting the difficult financial situation over a long period. In response to these problems, and with the opportunities offered by recent investment in the NHS, a major re-development of the BRI site is planned, and a new community hospital is going to be built in South Bristol. The two hospitals in North Bristol are to be merged on one site. There is substantial investment in re-developing other health care facilities in South Bristol using a public–private partnership. Therefore the health care facilities available in Bristol should be transformed within the next decade.

Section 3 Methods

3.1 Aim

To investigate the effectiveness, cost-effectiveness, accessibility and acceptability of a PCDS in comparison with a hospital outpatient clinic for dermatology.

3.2 Research objectives

- To determine the proportion of patients referred by GPs with dermatological problems who can be managed in a PCDS rather than a specialist dermatology hospital outpatient clinic.
- To determine whether a PCDS impacts on access to care for patients.
- To compare the effectiveness and cost-effectiveness of providing care in a PCDS or a hospital outpatient clinic. Costs will be assessed from a societal perspective with patient costs and NHS costs clearly distinguished.
- To determine patients' satisfaction with care received in the PCDS compared with a hospital outpatient clinic.

3.3 Overview of study design

The overall design was a randomised controlled trial, with patients who were potentially suitable for care in a PCDS randomised either to receive this type of service, or to receive care in a dermatology hospital outpatient department as usual.

The primary outcomes were patient's disease-related quality of life and access to care. The main secondary outcome was patient satisfaction with the consultation. Measures of process included a description of the treatments provided, waiting times and the proportion of people referred by GPs to dermatology who were suitable for a primary-care-based specialist service.

An economic analysis was conducted, with costs assessed both from the perspective of the patient and of the NHS, to assess the cost-effectiveness of the new primary-care service in comparison with usual outpatient care.

There were advantages and disadvantages associated with the decision to randomise individual patients, rather than to conduct a cluster trial, randomised at the level of the general practice. A cluster trial, randomised by practice, would allow direct referral of patients to the PCDS, would probably make it easier to recruit patients, and would reduce scope for contamination if participation in the study improved GPs' management of patients randomised to the control arm. It would

also provide evidence about the question of induced demand, if practices with access to PCDS increased their referral rate to dermatology in comparison with control practices. This question could not be addressed directly in an individually randomised trial.

On the other hand, a cluster-randomised trial would have considerably less statistical power, especially given the relatively small number of practices and the high variability between their patient populations. There would also be a greater chance of baseline imbalance between the arms. Given that the study and the PCDS did not have any direct impact on the referring GPs, and that the clinical management of patients in the two services was likely to be similar, contamination is unlikely to be a major problem. Torgerson (2001) has recently pointed out that contamination has to be considerable before cluster-randomised trials are more efficient than individually randomised trials. Cluster randomisation would also lead to a potential problem with recruitment bias, especially in a study such as this where different groups of patients may have strong preferences to be seen in one setting or the other. Finally, there was a practical issue of gaining the support of the local primary-care community. Although the PCT were fully supportive of the trial, they did not think they would have the support of local GPs if the service was only available to half the practices. It would be necessary to gain the consent of practices to randomise them in a cluster-randomised design and if (as was anticipated) several practices declined involvement this would reduce the power and generalisability of the study. Moreover, in the likely event that this attrition would be differential across the arms, internal validity would have been compromised. On balance it was decided that an individually randomised design was preferable.

Given that it was not possible to provide evidence from the randomised controlled trial about the impact of the PCDS on referral rates and waiting times, a descriptive analysis was undertaken to examine these issues by comparing the BRI, the hospital provider in this study, with neighbouring trusts.

Further research was conducted to explore issues that are important to patients in relation to improving access to dermatology services. This was achieved using both qualitative and quantitative methods. In the qualitative study, patients with a range of characteristics and experiences of different services were interviewed in order to identify and explore the aspects of care patients with skin conditions deemed important in making choices about service use. This information was used to inform the development of attributes and levels to be used in a discrete-choice experiment which sought to quantify preferences for different aspects of access to dermatology services.

The following sections will describe the methods and results for each of the following elements of the research:

- randomised controlled trial (Sections 4 and 5),
- economic evaluation (Section 6),

- analysis of referral rates and waiting times (Section 7),
- qualitative research (Section 8),
- discrete-choice experiment (Section 9).

These sections will be followed by a discussion (Section 10), which will discuss the findings from each element of research and draw them together to consider the implications for the health service.

Section 4 Randomised controlled trial: methods

This section describes the randomised controlled trial to compare patients referred to the PCDS with those referred to the BRI, which is described as the hospital arm of the trial.

4.1 Subjects

Inclusion criteria were adult patients referred from any of the general practices (n=29) relating to Bristol South and West PCT to the Bristol Dermatology Centre at the BRI, with conditions deemed suitable by a consultant dermatologist or specialist GP for management in a primary-care clinic (see Suitability criteria of patients, Section 2.3.3).

Exclusion criteria were any patient deemed unsuitable for referral to the PCDS. This generally included conditions with no diagnosis, possible malignancies and requests for inpatient management. Although patients deemed unsuitable for referral to the PCDS were excluded from the trial, the proportion of all referrals and the range of problems deemed suitable or unsuitable for primary care were recorded.

Children aged less than 16 years were also excluded. The Bristol Dermatology Centre receives very few referrals about children, as most children are referred to Bristol Children's Hospital. It was felt that children may have different needs and assessment may require different outcome measures, and that the potential sample of children in the evaluation would be too small to allow analysis of them as a sub-group.

4.1.2 Identification of patients and recruitment

All referral letters from GPs were sent to the appointments clerk at the BRI in the first instance, who identified all letters from practices in Bristol South and West PCT. Details of all of these referrals were entered on a project database. The consultant and/or specialist GP read each referral letter and triaged patients as suitable or not suitable for the PCDS, based on the description of the problem in the referral letter. Potentially suitable patients were then sent a letter confirming that a referral about them had been received, explaining about the trial and inviting them to participate.

At the time of the study the BRI was operating a 'partial booking' appointment system in an attempt to reduce the number of patients who failed to attend initial appointments. Patients were sent a letter when their referral was received telling them that they had been placed on a waiting list. When they reached the top of the waiting list they were sent another letter inviting them to telephone to make an

appointment. Those who did not make contact within 2 weeks were removed from the waiting list.

During the trial patients were sent an initial booking letter which included information about the trial and asked them whether or not they wished to participate. If they agreed to participate in the trial they were asked to complete a baseline questionnaire. If they declined to participate they were asked if they were willing to give their reasons. If patients failed to respond in any way to this initial letter they were sent a reminder after 3 weeks, explaining that they would be removed from the waiting list if they did not reply. If no reply was received after a further 2 weeks these patients were removed from the waiting list and the referral letter was returned to the GP.

During the trial it became clear that a substantial number of patients were being removed from the waiting list because they did not respond to any letters. Although this is always a feature of partial booking systems, the proportion was higher than anticipated and there was a concern that this may be partly due to the extra paperwork being sent to patients as a result of the trial. Therefore the appointment records for these patients were re-examined retrospectively. If patients were re-referred by their GP during the trial recruitment period they were treated as non-responders to the trial. If they were not re-referred they were treated as having been removed from the waiting list and ineligible for the trial.

Patients were added to the dermatology waiting list at the BRI as soon as their referral letter was received. In this way, patients declining to participate, and those who participated and were randomised to an appointment at the BRI, were not disadvantaged by any delays incurred by the trial recruitment process, and waiting-list figures at the BRI were unaffected.

In addition to patient referrals sent to the dermatology department, patients with possible skin cancer were referred by fax directly to a special 'cancer office', under the 2-week wait scheme, and these referrals were not collected on the project database. Such patients are in any case excluded from being seen at the PCDS and were ineligible for the trial. Details of the number of these patients in the relevant period from South and West Bristol were collected at the end of the study.

4.2 Randomisation

Consenting patients were randomised to receive an appointment at either the PCDS or the hospital outpatients' clinic at the Bristol Dermatology Centre at the BRI. The latter will be referred to as the hospital arm. Randomisation was made at the level of the individual, stratified by practice. Randomisation used a computerised system remote to the point of recruitment. Patients were randomised in a 2:1 ratio in favour of the PCDS. The randomisation schedule was generated by the trial statistician (TP), and allocation made

independently by the research associate, based only on knowledge of the patient's practice, blind to any information about the patient or their clinical condition.

The fact that a trial was taking place could have meant that the PCDS did not operate at full capacity because some patients suitable for PCDS were randomised to the hospital. This would have been undesirable for several reasons. First, the PCDS would be less efficient because the resources would be underused. Second, patients at PCDS may have a different experience, perhaps with longer consultations, because the staff were under-employed. Third, waiting times at PCDS may be shorter and at the hospital may be longer than if the PCDS operated at full capacity. Therefore two measures were taken to try to ensure that the PCDS operated at the same capacity as it would have done if a trial had not being conducted. Randomisation in a 2:1 ratio in favour of PCDS increased the proportion of suitable cases sent there. In addition, the appointments clerks at the BRI were told about the number of people who were randomised to the BRI within the trial, and asked to offer appointments at the PCDS to an equivalent number of patients on the waiting list from other PCTs (hence not eligible for the trial).

4.3 Making appointments

Patients randomised to the PCDS were sent a letter by the BRI dermatology appointments clerk, informing them of their randomisation allocation and inviting them to telephone the PCDS to arrange an appointment.

Patients randomised to the hospital were sent a letter informing them of their randomisation allocation and that they would be contacted again when they reached the top of the waiting list. Once they had reached the top of the list they were sent another letter inviting them to telephone the hospital to make an appointment.

Patients declining involvement in the trial remained on the BRI waiting list and were seen in due course as usual.

During the trial period, patients could only be referred for a doctor's appointment at the PCDS as part of the trial. The specialist nurse at the PCDS did receive direct referrals of children, mainly for advice about self-management of eczema, but these patients were not eligible for the trial.

4.4 Outcome measures

4.4.1 Primary outcomes

The two primary outcomes were patients' disease-related quality of life and patient-perceived accessibility.

Disease-related quality of life

Disease-related quality of life was measured primarily using the Dermatology Life Quality Index (DLQI; Finlay and Khan, 1994). This is a generic measure of the impact of skin problems on quality of life. It has been tested for reliability and sensitivity to change, has been cross-validated with other quality of life measures, and has been widely used in studies in a range of settings (Finlay, 1997). However, previous experience suggests that it may have limited sensitivity to change for the less serious problems likely to be triaged as suitable for the PCDS (H. Williams, personal communication). Therefore a single item question to assess overall improvement in the skin problem, from the perspective of the patient, was also included.

The DLQI was used as the primary outcome because it is clearly fundamental that a new service is at least equivalent in terms of outcome, irrespective of other benefits such as improved accessibility or reduced costs, as it is otherwise unlikely to be supported by the NHS.

Accessibility

Accessibility is a multi-dimensional concept (Gulliford *et al*., 2001) and this study includes measures of several dimensions of access. These include the capacity of the system to supply services, patient perception of accessibility and acceptability, costs to patients of gaining access to the service, DNA rates and waiting times. The primary measure of access used in this study was patients' perceptions of the accessibility and convenience of care in the PCDS or in the hospital outpatients' clinic. Following interviews with patients in the waiting room at the PCDS and the BRI Dermatology Centre, a series of questions were devised to address issues of importance to them in relation to the accessibility of the service. The intention was to combine responses to several of these questions in a 'perceived access' scale, subject to such a scale having satisfactory measurement properties.

Other dimensions of access were treated as secondary outcomes.

4.4.2 Secondary outcomes

Patient satisfaction with the consultation

Patient satisfaction with their consultation was assessed using the Consultation Satisfaction Questionnaire (CSQ; Baker, 1990). As well as providing an overall satisfaction score, this also provides sub-scores about general satisfaction, professional care, depth of relationship and perceived time. In addition to the CSQ, further questions were devised and piloted to assess patients' satisfaction with the site of care and facilities at the services.

Secondary measures of access

Improved access to care was operationalised in several ways, treated as secondary outcomes.

- Patients were asked where they would prefer to receive care in future (PCDS or hospital), and reasons for their preference. These questions were asked at baseline and at the end of the study.
- The number of patients failing to attend their appointment (DNA rate) is a proxy for the accessibility of a service. This was assessed from clinic records.
- Decreased waiting times are an important component of access. Waiting times, from when the referral letter was received to when the patient had their first appointment, were compared for patients randomised to the PCDS or the hospital.

4.4.3 Process measures

Suitability for primary care

Data were collected about the number of patients in total referred for dermatological problems and the proportion suitable to be seen in the PCDS, along with the number of patients who were randomised to the PCDS but subsequently needing to be referred to the hospital clinic.

Follow-up rates, treatment provided, investigations

Data were collected from clinic records about the number of patients re-attending for follow-up appointments; the number referred from PCDS to the hospital (patients initially randomised to the hospital could not be transferred to PCDS during the trial); and the number and type of investigations, procedures and prescriptions provided at each site.

Reasons for referral

Referral letters were examined and coded to determine the main reasons for referral in terms of diagnostic categories. Once the resource use data had been collected then final diagnoses were determined, using the diagnosis from their final consultation.

4.5 Data collection

4.5.1 Timing of assessments

At baseline patients completed a questionnaire (questionnaire 1; Appendix 1) which collected demographic data, the DLQI and a opinions about their preference for site of care.

When patients attended their first consultation at the PCDS or hospital they were asked to complete a questionnaire after the consultation (questionnaire 2; Appendix 2). This collected details of patients'

resource use and costs in attending the consultation and since randomisation, their satisfaction (CSQ) and their perceptions of the accessibility and convenience of the service. Patients not returning a questionnaire were sent up to two reminder questionnaires by post.

Six weeks after their initial appointment, patients were sent a short questionnaire to assess their clinical improvement, using the DLQI and the single-item overall measure of improvement (questionnaire 3; Appendix 3). Non-responders were sent up to two reminders. At the second reminder, data were collected by telephone for patients who had provided telephone numbers. Because of variable waiting times, Questionnaire 3 provided data about clinical status at a relatively constant time after the intervention was provided, but at a variable period after randomisation.

Primary assessment of outcomes was made 9 months after randomisation. Questionnaire 4 (Appendix 4) collected data about clinical outcomes (DLQI and the single-item measure), patients' resource use and costs in attending consultations and in using prescribed and non-prescribed medication between their first appointment and end of follow-up, and preference for site of future care and reasons for that preference.

The original intention had been to assess outcomes 6 months after randomisation. However, it became clear that because of lengthy waiting lists, particularly at the hospital, the 6-month follow-up (questionnaire 4) could occur in some cases *before* questionnaire 3 was administered 6 weeks after the first appointment. Some of these patients may not have yet attended any follow-up appointments and this effect was different in the two arms of the trial because of different waiting lists. Following analysis of pilot data showing that the majority of patients had been seen and completed any follow-up by 9 months after randomisation (although a small number were still being seen after this), it was decided to extend the period of follow-up from 6 to 9 months after randomisation. This was felt to be the optimum time period to capture most of the data while minimising loss to follow-up from respondents.

Although the main cost-effectiveness analysis was based on outcomes and costs at 9 months, data were collected on health-service costs up to 12 months, allowing sensitivity analysis to see if costs were simply deferred because of waiting-list effects.

Data about NHS resource use were obtained from records at the PCDS and the hospital. Data about consultations and prescriptions for skin problems were collected from GP records.

Data about reasons for referral were obtained from the original referral letters. Data about non-attendance rates and follow-up rates were obtained from clinic records.

4.6 Analysis

4.6.1 Baseline assessment

An initial descriptive analysis compared the two randomised groups at baseline in terms of demographic variables, range of problems for which referred, DLQI, preference for future care (and reasons for preference) and the success of randomisation in achieving balance across the trial arms in terms of the stratification variable of practice.

4.6.2 Primary outcomes

DLQI and overall clinical improvement

The primary comparative analysis used multiple regression models to compare the DLQI at 9 months between the trial arms, adjusting for baseline DLQI and stratification (practice).

Analysis was conducted on the principle of 'intention to treat'. Although the primary analyses included only those completing the DLQI at 9 months, a sensitivity analysis was conducted where missing follow-up data were assumed to be the same as the last recorded measurement.

Each of the 10 items on the DLQI is scored from 0 to 3 and the overall score is presented as the sum of all items for that patient. Therefore possible scores range from 0 (no impairment in quality of life) to 30 (worst impairment). Where one item on the DLQI was missing for a particular patient, this was replaced with the mean of the other items for that patient. If more than one item was missing the scale was scored as missing.

The distribution of scores on the DLQI was found to have a strong positive skew; therefore medians and interquartile ranges were calculated as well as means. Analysis of differences between trial arms was based on the log DLQI score and hence the ratio of geometric means was used for statistical comparisons. Because it is not possible to calculate the log of zero, all responses on the DLQI were increased by 1 before scores were log-transformed (using base 10).

The single-item measure of patient-perceived improvement in their skin was compared with a five-point Likert-type scale using a proportional odds regression model for an ordered categorical variable, again adjusting for practice. The assumptions of this model were assessed and found to be upheld.

Both the DLQI and the single-item measure of improvement were analysed for the data collection points at 6 weeks post appointment (time 3) and 9 months post randomisation (time 4). The latter was used as the primary time point for outcome assessment.

The data about DLQI collected at time 3 were related to the appointment date, but a variable period after the date of

randomisation. Therefore the comparison between arms was conducted using a regression model adjusted for baseline DLQI, practice and time (days since randomisation).

Patient perceptions of access

An initial factor analysis was conducted to examine whether the questions about patient perceptions of access formed a coherent scale. Cronbach's alpha statistic was used to assess the reliability of the resulting scale, comprising three questions. Comparison between trial arms of the perceived access scale was made using multiple regression models adjusted for stratification by practice.

To calculate the access scale, the mean score for each of the three questions was calculated for each patient, and then re-calculated so that the mean was presented from 0 to 100, representing the percentage of the maximum possible score. If one question item was missing this was replaced with the mean of the other questions in the scale; if more than one item was missing the scale was scored as missing.

4.6.3 Secondary analysis of primary outcomes

Secondary analyses were planned to adjust for key prognostic variables exhibiting imbalance at baseline, judged using descriptive statistics for the trial arms at baseline.

A planned sub-group analysis of differences in the primary outcomes (DLQI, global perception of improvement, access score) was conducted according to initial preferences, using an appropriate interaction term in the regression models.

4.6.4 Secondary outcomes

Patient satisfaction with the consultation

CSQ scale scores were calculated as the mean score for all items in the scale. If one question item was missing this was replaced with the mean of the other questions; if more than one item was missing the scale was scored as missing. The mean score was calculated for each patient and then re-calculated as the percentage of the maximum possible score, where a score of 100 represents maximum satisfaction and 0 represents maximum dissatisfaction.

Comparison of CSQ scores between trial arms was made using multiple regression models adjusted for stratification by practice.

Satisfaction with facilities

Three questions about the receptionists, the waiting room and the consulting room also formed a scale identified using factor analysis and this was analysed in the same way as the scale about patient perceptions of access.

Preference for site of care

Patients' preferences at baseline were analysed descriptively, and preference at the end of the study was adjusted for baseline preference.

DNA rates

The number of patients failing to attend their first appointment, and the proportion of all appointments not attended (first and follow-up appointments combined) was compared between the arms using logistic regression and linear regression models respectively.

Waiting times and referral rates

The mean waiting time in days between the date of the referral letter being received and patients having their first appointment was compared between trial arms using an appropriate regression model adjusted for practice.

Further analysis of dermatology waiting times at the hospital compared with neighbouring trusts is described in Section 7.

4.6.5 Process measures

Descriptive statistics were used to present data about the process measures described in Section 4.4.3.

4.6.6 General

All comparisons were made for the PCDS relative to the hospital. Therefore odds ratios greater than one are in favour of the PCDS. Analyses were conducted using Stata v8.

4.7 Sample size

Sample-size calculations were based on seeking to establish equivalence between the primary-care service and the hospital outpatient clinic in terms of effectiveness (the DLQI). From nQuery Advisor version 4.0 software, a sample size of 290 patients in the primary-care arm and 145 patients in the hospital arm would provide 80% power to rule out differences larger than 0.285 standard deviations in either direction, on the basis of two-sided 95% confidence intervals and assuming no difference between the two groups in terms of (true) effectiveness. Differences smaller than this would not be considered clinically important.

The trial was powered as an *equivalence* study to rule out differences in the DLQI. For access measures the sample-size justification would more reasonably relate to detecting a *difference* between the trial arms. The trial had 80% power to detect a difference of 0.29 standard deviations in any continuous variable reflecting access, such as the patient perceptions of access scale, waiting times or the cost to

patients of gaining access. For measures represented by dichotomous variables such as patient preference for the setting for a future appointment, the sample size would have 80% power to detect differences of between 11 and 15 percentage points (for example, 10 and 21%, and 45 and 60%) using a two-sided 5% significance level.

4.8 Piloting

4.8.1 Estimating recruitment

In a pilot study, 266 consecutive non-urgent referral letters to the Bristol Dermatology Centre were assessed. Just over half (138/266; 52%) were judged to need an appointment at the hospital and 48% were potentially suitable for a PCDS. Based on a consent rate of 65% and an attrition rate of 20%, 1744 referrals would be needed to approach 837 suitable patients and recruit 544 to obtain the target sample size of 435 patients. Based on an estimate of 140 referrals from south and west Bristol per month, of which 45% would be eligible for the primary-care service, it would take 13 months to recruit sufficient patients for this study.

4.8.2 Trial methodology

The PCT agreed to formally evaluate the PCDS and to take account of this in planning the service from the outset. However, the timescale for obtaining research funding did not easily fit with the timescale needed to plan the service itself. It was agreed to establish the service as a 'shadow' randomised controlled trial from its inception, while external funding for a randomised trial was being sought. Much planning was needed to ensure smooth arrangements for the transfer of patients between the hospital and the PCDS, and it would have been very difficult to re-negotiate these arrangements soon after they had started in order to randomise patients for a trial, if this was not anticipated from the beginning.

Therefore the procedures for the collection of data about referrals, the recruitment and randomisation of patients and the administration of questionnaires were developed from when the PCDS was first established in January 2002. This provided an invaluable opportunity to pilot and improve procedures for a full trial. This pilot period was made possible because of the short-term secondment to the University of Bristol of a GP registrar on an academic attachment, and the determination of the PCT, the hospital trust and the university to support evaluation on a short-term basis from their own resources until external funding could be obtained.

By the time the funded trial began in September 2002 the evaluation procedures were well developed and the formal trial was able to proceed without delay.

4.9 Project management

4.9.1 Ethical-committee approval and research governance

The project was managed in accordance with the Research Governance Framework. Ethical approval was obtained from United Bristol Healthcare Trust Local Research Ethics Committee (ref. E5221), and research governance approval obtained from Bristol South and West PCT and United Bristol Healthcare Trust.

4.9.2 Trial Steering Group

A Trial Steering Group was established, consisting of an experienced trial researcher as an independent chair, two lay representatives, a primary-care lead of the PCT and two independent consultant dermatologists. Because no interim analyses were planned it was not considered necessary to have an independent data-management committee.

Section 5 Randomised controlled trial: results

5.1 Referrals and recruitment

During the recruitment period (1 September 2002–31 October 2003), 2028 referral letters were received and assessed for eligibility. From the referral letters, 335 referrals were not eligible because they were made through the fast-track scheme for suspected cancer, and 987 (49%) appeared to be suitable for the PCDS. Of these, 219 patients were removed from the waiting list because they no longer needed an appointment, could not be contacted or for other reasons. Of the remaining 768 eligible patients, 556 (72%) agreed to participate in the trial and were randomised, 354 patients to the PCDS and 202 to the hospital. Of those patients in the trial, 88% (488/556) attended their first appointment, 78% (435/556) completed questionnaire 2 after their appointment, 78% (432/556) completed questionnaire 3 6 weeks after their appointment and 76% (422/556) completed questionnaire 4 at the final 9-month follow-up.

Of those 219 patients who could not be contacted and were removed from the waiting list, 82 were re-referred to dermatology outpatients during the recruitment period. If these patients are included in the denominator as not wishing to participate in the trial, the effective recruitment rate was 65% (556/850). Figure 2 shows a CONSORT diagram illustrating the flow of patients through the study.

Appendix 5 shows the recruitment process in relation to recruitment targets. The number of patients referred was lower than anticipated but the proportion suitable for the PCDS was higher. Recruitment took a total of 14 months instead of the 13 months planned.

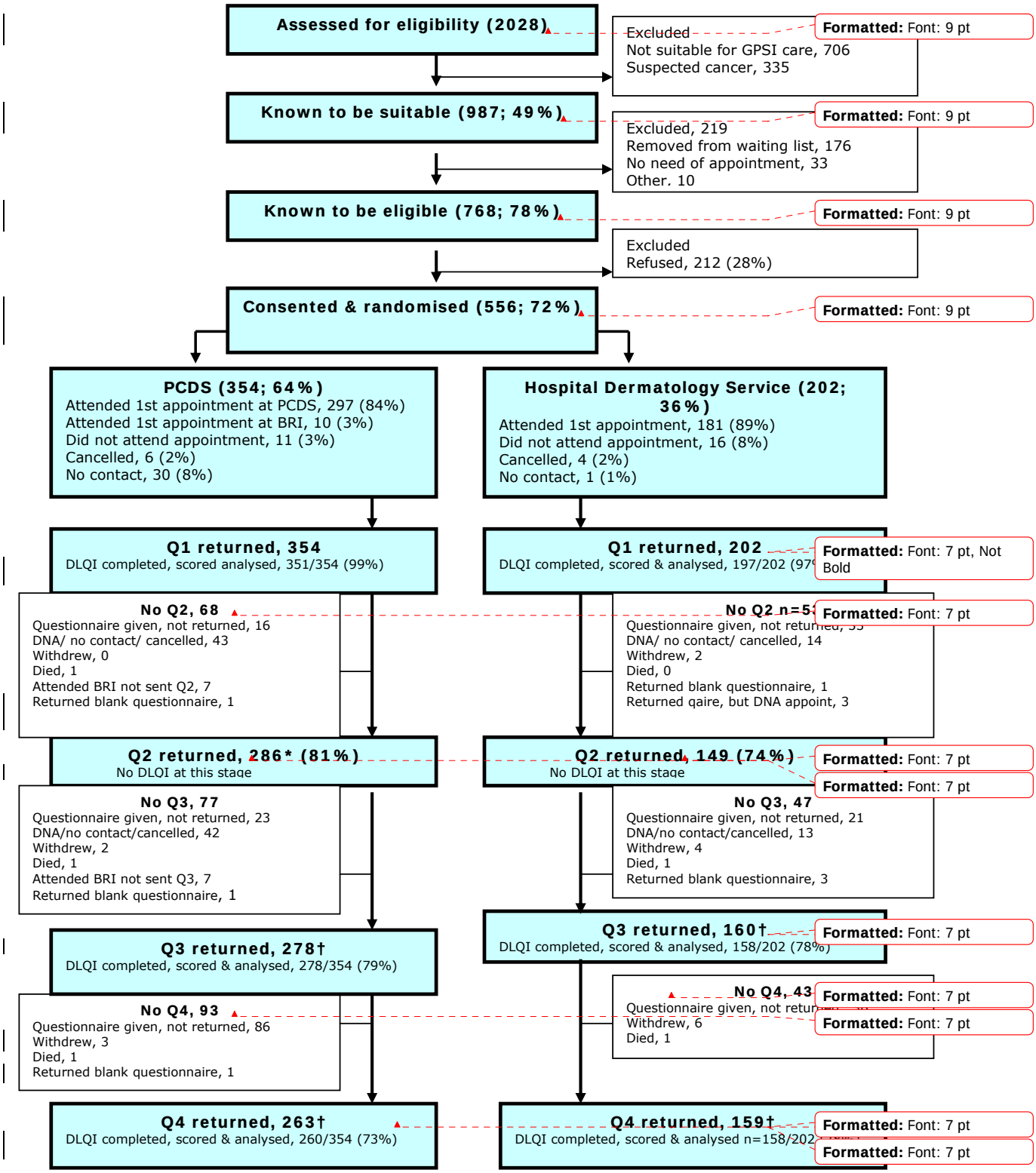
5.2 Baseline assessment

Table 2 shows the age and sex characteristics of patients recruited in comparison with all those referred and all those potentially suitable for the PCDS. This shows that the patients recruited were representative of all patients referred.

Table 2 Age and sex characteristics of patients referred, potentially suitable and consented

	Referred (*n*=1693)	**Suitable (*n*=987)**	**Consented (*n*=556)**
Female (%)	993 (59%)	602 (61%)	335 (60%)
Age (years)			
Mean (±SD)	48 (21)	47 (20)	48 (19)
Median (±range)	46 (7–103)	44 (16–97)	47 (16–95)

Figure 2 CONSORT diagram: flow of patients through the trial



**Includes three patients who attended BRI instead of the PCDS.*

†Some patients returned Q3 who did not return Q2, and/or returned Q4 without returning Q3. The number of patients returning Q3 also includes one patient in the PCDS arm and five patients in the hospital arm who returned Q3 but did not attend their initial appointment.

The main reasons for patients declining to give consent to the trial are given in Table 3. Most of these reasons related to an unwillingness to attend the PCDS, mainly because of its location, rather than unwillingness to participate in research.

Table 3 Reasons for declining to participate in trial

Reasons for refusal	Number (%)
Prefer BRI, more convenient	45 (22%)
Too busy/no time/work commitments	19 (9%)
Problem not severe/too minor/not a skin problem	18 (9%)
Too old/too ill	15 (7.5%)
Poor transport	14 (7%)
Prefer to see consultant	14 (7%)
Location of PCDS	13 (6.5%)
Study not relevant/does not apply	8 (4%)
Prefer to not take part	6 (3%)
Want to be seen as soon as possible and sort out problem	3 (1.5%)
Other (moving, language problem, too stressful, happy with diagnosis, insufficient information, don't know, too shy, gone privately)	11 (5.5%)
No reason	36 (18%)
	Total=202

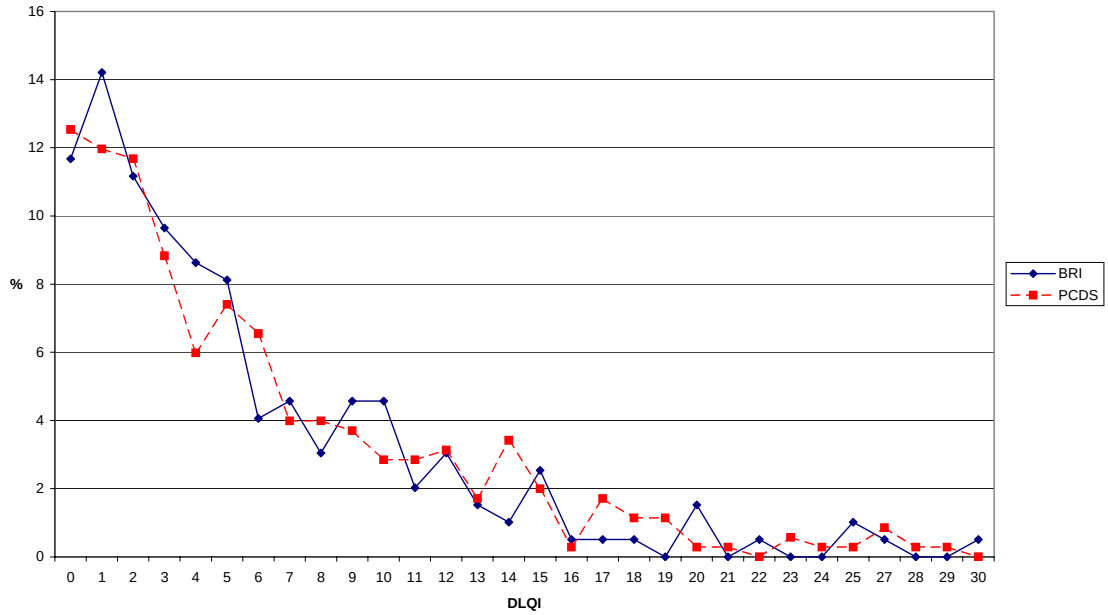
Missing data=10.

Table 4 shows the characteristics at baseline of patients randomised to each arm of the trial. This shows that the groups were similar in respect of all the variables examined. The apparent difference in mean DLQI scores at baseline is due to the skewness of the data (see Figure 3). The median DLQI scores are identical in the two groups and show that most participants' skin conditions impacted relatively lightly on their quality of life, although a minority experienced more severe problems.

Table 4 Characteristics of randomised groups at baseline

	PCDS (*n*=354)	Hospital (*n*=202)
Mean age (±SD)	47.6 (19)	48.5 (19)
Age groups (*n*; %)		
16–24 years	42 (12%)	23 (12%)
25–34 years	67 (19%)	38 (19%)
35–44 years	57 (16%)	35 (17%)
45–54 years	56 (16%)	21 (10%)
55–64 years	46 (13%)	37 (18%)
65–74 years	52 (15%)	28 (14%)
75+ years	34 (9%)	20 (10%)
Sex		
Female (%)	213 (60%)	122 (60%)
DLQI		
Mean (±SD)	6.06 (5.59)	5.61 (5.67)
Median	4	4
Interquartile range	2–9	1–8

Figure 3 Distribution of DLQI score by group



Overall, 328/537 (61%) patients expressed a preference for care at the PCDS rather than the hospital. Table 5 shows the main reasons for this preference. This is expressed in terms of the reasons that each site was preferred, rather than in terms of the groups to which patients were randomised, since these data about preferences were collected before patients were aware of their allocation.

Table 4 Reasons for preference for each site of care

Reasons for preference	PCDS (number preferring PCDS, 323)	%	Hospital (number preferring hospital, 141)	%
Location	187	58%	71	50%
Easy of parking	88	27%	3	2%
Easy access	46	14%	23	16%
Convenient	42	13%	17	12%
Specialised care	13	4%	7	5%
Less waiting time	18	6%	-	
Previous appointment here	–		11	8%
Good bus service	2	1%	7	5%
No parking at BRI	7	2%	–	
No transport	2	1%	5	3%
To help research	4	1.2%		
Want to see consultant	–		2	1.4%
Other (less stressful, to solve problem, something different, café there)	5	1.5%	4	3%
No preference/not sure	3	1%	2	1.4%

Note: some respondents reported more than one answer.

The success of the randomisation in achieving balance across the trial arms in terms of the stratification by practice is shown in Appendix 6.

5.3 Primary outcomes

5.3.1 DLQI and overall clinical improvement

The primary statistical comparison between the trial arms was of the log DLQI at 9 months, adjusting for log DLQI at baseline and stratification (practice). Since this follow-up period occurred at a variable interval after the intervention (the first appointment), a secondary analysis examined the difference between the log DLQI at time point 3, 6 weeks after the initial appointment. These comparisons are shown in Table 6.

Note that the mean scores in the two arms are different at baseline but the median scores are the same. This is due to the skewed distribution of the data.

Table 5 Primary outcome: DLQI at follow-up

	PCDS		Hospital				
DLQI*	***Mean (±SD)***	***Median (IQR)***	***Mean (SD)***	***Median (IQR)***	***Ratio of geometric means***	***95% CI***	***P value***
Baseline (*n*=548)	6.06 (5.95)	4 (2–9)	5.61 (5.67)	4 (1–8)			
6 weeks post appointment (*n*=436)	3.75 (4.59)	2 (0–5)	2.63 (3.94)	1 (0–3)	1.13‡	0.96–1.33	0.14
9 months post randomisation (*n*=418)	2.83 (4.28)	1 (0–4)	2.70 (4.24)	1 (0–3)	0.99¶	0.85–1.15	0.88

Single item measure of improvement†	***Median (IQR)***	***Median (IQR)***	***Odds ratio***	***95% CI***	***P value***
6 weeks post appointment (*n*=430)	4 (3–5)	4 (3–5)	1.05	0.73–1.50	0.80
9 months post randomisation (*n*=409)	4 (3–5)	4 (3–5)	1.17	0.81–1.70	0.40

**Higher DLQIs represent worse quality of life.*

†Higher scores on the single-item measure indicate greater improvement.

‡Adjusted for baseline, stratification and time since randomisation; n=429 at 6 weeks post appointment.

¶Adjusted for baseline and stratification; n=412.

CI, confidence interval; IQR, interquartile range.

Table 6 suggests that there was no statistically significant difference between the two arms of the trial in terms of disease-related quality of life and also in terms of patients' perceptions of improvement. The point estimate suggests that patients' quality of life (DLQI) was almost identical in the two arms after 9 months, although the confidence intervals are consistent with patients at the PCDS having a quality of life which is 15% better or worse than those attending the hospital. Since this represents only a difference of about 1.5 points on the DLQI measure, the findings suggest that meaningful differences between the two arms are very unlikely.

A sensitivity analysis of the DLQI incorporating the last observation carried forward to replace missing data had virtually no effect on these results.

The above findings could be interpreted as suggesting that patients obtain equally good clinical improvement whether they attend the PCDS or the hospital. However they are also not inconsistent with a hypothesis that patients' skin-related quality of life improves with time, irrespective of treatment arm, and this hypothesis cannot be disproved since the trial did not include a 'no-treatment' arm.

5.3.2 Patient perceptions of access

A series of questions in questionnaire 2 addressed issues related to the accessibility of the service, the receptionists, and the waiting area and facilities. An initial factor analysis was conducted to examine whether these questions formed coherent scales. A varimax rotation was used to maximise the separation between factors. Two scales were identified which were labelled as access and facilities. One question about public transport was scored as not applicable by 53% (217/406) of respondents and did not contribute to either scale. The reliability of each scale was assessed using Cronbach's alpha statistic. The factor loading values for the two scales and their alpha statistics are shown in

Appendix 7.

Table 7 shows the scores on the access scale for the two arms of the trial. This shows that the PCDS was perceived to be more accessible than the hospital.

Table 6 Primary outcome: access to care

	PCDS mean (±SD; *n*=286)	**Hospital mean (±SD; *n*=149)**	**Difference in means***	**95% CI**	***P* value**
Access scale	76.13 (±19.34)	60.47 (±17.13)	14.85	10.79–18.91	<0.001

This table is based on 435 responses to questionnaire 2.

**Multiple regression analysis adjusted for practice. Access scale scored from 0 to 100. High scores represent better access.*

The access score presented above combines results from three questions and it may be more informative to compare the results about each individual question item. This information is shown below (Table 8). Table 8 includes the results from the fourth question about access which was not included in the final access scale.

5.3.3 Secondary analysis of primary outcomes

Secondary analyses to adjust for differences in key prognostic variables at baseline were planned, but were not needed as the trial arms appeared to be well balanced.

Table 7 Access to care: responses to individual question items

Question item	PCDS		Hospital	
	N	**%**	***N***	**%**
It was very easy to travel to my appointment	***278***	***97***	***146***	***98***
Strongly agree	118	42	35	24
Agree	116	42	70	48
Neither agree nor disagree	18	6	20	14
Disagree	19	7	17	11
Strongly disagree	7	3	4	3
It was very difficult to find a parking space	***270***	***94***	***130***	***87***
Strongly agree	6	2	27	21
Agree	12	4	17	13
Neither agree nor disagree	15	6	8	6
Disagree	97	36	18	14
Strongly disagree	93	34	4	3
Not applicable	47	17	56	43
Finding where to go for my appointment was difficult	***276***	***96***	***140***	***94***
Strongly agree	11	4	3	2
Agree	19	7	10	7
Neither agree nor disagree	20	7	19	14
Disagree	140	51	84	60
Strongly disagree	86	31	24	17
It was easy to get public transport to my appointment*	***264***	***94***	***142***	***87***
Strongly agree	13	5	23	16
Agree	33	13	40	28
Neither agree nor disagree	27	10	12	9
Disagree	17	6	9	6
Strongly disagree	11	4	4	3
Not applicable	163	62	54	38

**This question was not included in the access scale.*

5.4 Secondary outcomes

5.4.1 Patient satisfaction with the consultation

Patients attending the PCDS appeared to be slightly more satisfied with their consultations than those attending the hospital (Table 8). Although this finding has a small probability of being due to chance, it is unlikely to represent much of a meaningful difference for patients as the absolute differences were small. Analysis of the CSQ sub-scales shows that the greatest difference was in terms of the levels of perceived time, which is consistent with the longer appointments offered at the PCDS. There was also a slight difference in the patients' perceptions of the level of professional care, but no difference in the depth of the relationship.

5.4.2 Satisfaction with facilities

Three questions formed a scale labelled as facilities (see

Appendix 7). Patients attending the PCDS were slightly more satisfied with the facilities than those attending the hospital (Table 8).

Table 8 Patient satisfaction with the consultation and with facilities

	PCDS mean (±SD; *n*=286)	Hospital mean (±SD; *n*=149)	Difference in means*	95% CI	*P* value
CSQ					
Overall CSQ (*n*=386)	71.05 (±13.50)	65.93 (±17.17)	4.09	0.92–7.25	0.01
Subscales					
General satisfaction (*n*=418)	76.18 (±18.04)	68.78 (±23.29)	5.85	1.76–9.93	0.01
Professional care (*n*=413)	77.89 (±15.49)	72.02 (±19.82)	4.69	1.15–8.24	0.01
Depth of relationship (*n*=405)	60.03 (±16.41)	58.69 (±17.94)	0.68	−2.84–4.21	0.70
Perceived time (*n*=419)	69.02 (±18.99)	61.57 (±22.86)	6.59	2.36–10.81	0.002
Facilities scale					
(*n*=413)	79.83 (±13.56)	74.71 (±16.21)	4.59	1.60–7.58	0.003

This table is based on 435 responses to questionnaire 2. Denominators vary for different scales because of missing data.

**Multiple regression analysis adjusted for practice.*

Full details of patients' responses to the individual questions which make up the CSQ and the facilities scale can be seen in Appendix 8.

5.4.3 Preference for site of future care

Patients expressed their preferences for attending the PCDS or the hospital at baseline, with 61% (328/537) preferring to attend the PCDS, for the reasons given in Table 5. Patients were asked about their preference for future care at the end of the study. The results are shown in Table 10.

Table 10 Patients' preference for site of future care

	Randomisation arm				All patients	
	PCDS		Hospital			
	n	%	*n*	%	*N*	%
Initial preference						
PCDS	213/343	62%	115/194	59%	328/537	61%
Hospital	86/343	25%	60/194	31%	146/537	27%
No preference	44/343	13%	19/194	10%	63/537	12%
Preference for future care						
PCDS	199/260	76%	56/156	36%	255/416	61%
Hospital	52/260	20%	86/156	55%	138/416	33%
No preference	9/260	4%	14/156	9%	23/416	6%

Denominators vary because of missing data.

An interaction test between baseline preference and trial arm in respect of final preference gave a *P* value of <0.001. An examination of the data in Table 10 shows that although most people at baseline expressed a preference for the PCDS, after they had attended an appointment people were more likely to express a preference for future care in the site in which they had actually been seen.

Primary outcomes in relation to initial preference for site of care

The interplay between preference for site of care at baseline and randomisation in respect of the primary outcomes was examined with a series of interaction tests. There was an interaction between initial preference and trial arm in respect of the DLQI at 9 months, adjusted for baseline DLQI (*P*=0.016). The people who preferred the hospital at baseline and were randomised to it had worse quality of life at 9 months (median DLQI=2) than either those with this preference but randomised to PCDS (median DLQI=1) or all those who initially preferred PCDS regardless of trial arm (median DLQI=1). There was no corresponding interaction between baseline preference and randomisation in respect of the single-item measure of improvement. There was an interaction between baseline preference and trial arm in respect of access to care (*P*<0.001), with the highest access scores being observed in those preferring and being randomised to the PCDS and the lowest mean access scores observed among those initially preferring PCDS but randomised to the hospital. No such differences were observed among those initially preferring the hospital. One interpretation of this finding could be that many people preferring the PCDS did so because it was more accessible, whereas those preferring the hospital may have done so for reasons other than access. This interpretation would be consistent with the reasons given by respondents for their initial preferences, shown earlier in Table 5.

5.4.4 Failure-to-attend (DNA) rates

A total of 300/354 (85%) of patients randomised to PCDS attended their first booked appointment, although due to administrative errors 10 of these patients attended the hospital.[a] These patients were analysed in the PCDS arm on an 'intention to treat' basis. Only 18/354 (5%) of patients failed to attend their first booked appointment from the PCDS arm, but 30 (8%) patients failed to book an appointment at all and 6 (2%) patients cancelled. The DNA first appointment rate (the proportion of first appointments booked which were not attended) was 6% (18/318).

In the hospital arm 176/197 (89%) of patients attended their first booked appointment. Only 5 (2%) patients cancelled their appointment or did not make an appointment, and the DNA first appointment rate was 11% (21/197).

It appears that people randomised to the PCDS did not contact it to make an appointment if they do not wish to attend, whereas in the hospital a higher proportion of first appointments were wasted because patients failed to attend (odds ratio, 0.50; 95% confidence interval (CI), 0.26–0.97; *P*=0.04).

Including follow-up appointments, the 556 patients in the trial had a total of 1083 booked appointments. The DNA rate for all appointments was similar in the two arms of the trial (9-month data: PCDS arm, 8% (60/742); hospital arm, 11% (37/341); odds ratio, 0.72; 95% CI, 0.47–1.11; *P*=0.14. 12-month data: PCDS arm, 8% (61/789); hospital arm, 10% (39/382); odds ratio, 0.74; 95% CI, 0.48–1.12; *P*=0.16). Because a proportion of patients randomised to the PCDS were referred to the hospital for follow-up, and a small number of patients randomised to PCDS attended the hospital for their first appointment in error, these data are shown in more detail in Table 11.

Table 9 DNA rates for new and follow-up appointments

		Randomisation				All patients (*N*=515)*	
	Time period (months)	PCDS (*N*=318)*		Hospital (*N*=197)*			
		DNA rate	%	DNA rate	%	DNA rate	%
Initial booked appointment							
PCDS	–	15/305	5%	0/0	0%	15/305	5%

[a] Note: First booked appointment means the first appointment that was booked for that patient. Some of those patients who failed to attend this appointment attended a subsequent appointment, which became the first appointment they actually attended. Therefore the number of people attending their first appointment at the PCDS or BRI as shown in the CONSORT diagram (Figure 2) is greater than the number of people attending their first *booked* appointment in Table 9.

Hospital	–	3/13	23%	21/197	11%	24/210	11%
Total	–	18/318	6%	21/197	11%	39/515	8%
All appointments†							
PCDS	9	39/639	6%	0/0	0%	39/639	6%
	12	39/674	6%	0/0	0%	39/674	6%
Hospital	9	21/103	20%	37/341	11%	58/444	13%
	12	22/115	19%	39/382	10%	61/497	12%
Total	9	60/742	8%	37/341	11%	97/1083	9%
	12	61/789	8%	39/382	10%	100/1171	9%

**Number of people with at least one booked appointment, including appointments they failed to attend.*

†New and follow-up appointments combined.

5.4.5 Waiting times

Patients in the trial

The mean waiting time between the date of the referral letter being received and patients having their first appointment was much shorter for patients randomised to the PCDS compared with the hospital (mean wait, 72 days compared with 113 days, respectively; mean difference, 40 days; 95% CI, 35–46 days; $P < 0.001$).

Since patients were added to the hospital waiting list when their initial GP referral letters were received, the process of recruitment to the trial and randomisation did not affect waiting times for those in the hospital arm. However for patients randomised to the PCDS, it is arguable that a more appropriate measure of waiting time is the time between the letter being received and being triaged plus the time between when the referral was passed from the hospital to the PCDS and the patient was invited to make an appointment. The process of recruitment and randomisation will have added to the waiting times that these patients would have experienced if the trial had not been in existence. The mean delay for patients randomised to the PCDS between the date the referral letter was triaged as being suitable for the PCDS and a letter being sent inviting these patients to make an appointment following recruitment and randomisation was 25 days (SD, 12 days). Therefore the reduction in waiting time for patients sent to the PCDS would have been greater still, by an average of 25 days, if the trial had not taken place.

5.5 Process measures

5.5.1 Suitability for primary care and types of condition

As can be seen from the data presented in the CONSORT diagram (Figure 2), about half (987/2028; 49%) of all the patients referred to the dermatology department appeared to be suitable for management in a primary-care-based specialist service, based on the referral letter.

Referral letters triaged as being suitable for the PCDS were coded retrospectively by the research team to determine the main types of referral. Data about diagnoses made at the final appointment were obtained from clinic records and also coded. The findings are shown in Table 12.

Table 12 Reasons for referral and diagnostic categories

Reason for referral	**GPSI (*N*=354)**	**Hospital (*N*=202)**	**Combined (*N*=556)**
Eczema, psoriasis	89 (25%)	52 (26%)	141 (25%)
Urticaria, pruritis	21 (6%)	13 (6%)	34 (6%)
Benign lesion (e.g. seborrhoeic wart, cyst, naevus)	32 (9%)	15 (7%)	47 (8%)
Undiagnosed rash	45 (13%)	16 (8%)	61 (11%)
Undiagnosed lesion	45 (13%)	24 (12%)	69 (12%)
Keratoses, basal cell carcinoma	31 (9%)	23 (11%)	54 (10%)
Moles, pigmented lesions	24 (7%)	13 (6%)	37 (7%)
Infective condition	10 (3%)	9 (4%)	19 (3%)
Acne, rosacea	13 (4%)	10 (5%)	23 (4%)
Other (e.g. leg ulcer, oedema, hirsutism, hyperhydrosis, vitiligo)	44 (12%)	27 (13%)	71 (13%)

Diagnostic category at final clinic appointment	**GPSI N=307**	**Hospital N=181**	**Combined N=488**
Diagnosed rash (e.g. eczema, psoriasis, urticaria)	140 (46%)	70 (38%)	210 (43%)
Benign lesion (e.g. seborrhoeic wart, cyst, naevus)	78 (25%)	54 (30%)	132 (27%)
Undiagnosed rash	14 (4%)	3 (2%)	17 (4%)
Undiagnosed lesion	11 (3%)	4 (2%)	15 (3%)
Keratoses, basal cell carcinoma	17 (5%)	13 (7%)	30 (6%)
Pustular or infective condition (acne, skin infection, folliculitis)	17 (5%)	14 (8%)	31 (6%)
Other (leg ulcer, oedema, pruritus, hirsutism,	27 (9%)	18 (10%)	45 (9%)

hyperhydrosis)			
Pending	3 (1%)	5 (3%)	8 (2%)

5.5.2 Follow-up rates, treatment provided, investigations

All patients in this study had been triaged as suitable for primary-care management in the PCDS. However it was anticipated that in some cases GPSIs working in the primary-care service would need to refer patients to the consultant dermatologist at the hospital for either further advice or specialised treatment not available at PCDS. Of those patients having their first appointment at the PCDS, 38/307 (12%) were referred for follow-up at the hospital.

In addition, it was important to examine follow-up rates for patients randomised to each site, to explore the possibility that GPSIs would have a different threshold for asking patients to return for further appointments compared with doctors working in hospital. These data are shown below (Table 13).

Table 10 Follow-up rates

		PCDS		Hospital	
		N*=307	**%**	***N*=181***	**%**
Proportion of patients followed up at:					
PCDS		158/297	53%	–	–
Hospital, initial appointment at PCDS		35/297	12%	–	–
PCDS, initial appointment at hospital		1/10	10%	–	–
Hospital, initial appointment at hospital		3/10	33%	79	44%
Both sites		181/307†	59%	79	44%
Mean number of appointments (initial and follow-up) at:		***Mean***	***95% CI***	***Mean***	***95% CI***
PCDS	9 months	2.03	1.87–2.19	–	–
	12 months	2.13	1.95–2.31	–	–
Hospital	9 months	1.95	1.61–2.30	1.72	1.55–1.88
	12 months	2.07	1.72–2.41	1.90	1.69–2.09
Both sites	9 months	2.24	2.07–2.42	–	–
	12 months	2.37	2.18–2.56	–	–
		Ratio‡		***Ratio‡***	

New to follow-up appointments	9 months	1:1.24	1:0.72
	12 months	1:1.37	1:0.90

**The denominator is the number of patients in this arm attending at least one appointment.*

†Some people may have had follow-up appointments at both sites.

‡Excludes appointments which were not attended or cancelled.

Table 13 shows that the GPSIs at the PCDS tended to follow-up a higher proportion of patients than did the doctors at the hospital.

There may also be differences in the number and type of investigations, procedures and prescriptions provided at each site. Further details of these aspects of care are described in Section 6, the economic analysis, as these are important issues of resource use.

Section 6 Economic evaluation

6.1 Aim

The intention of the economic evaluation was to compare the costs and benefits of the hospital outpatient department with those of the new PCDS. These two proposed methods of providing dermatology services were compared by answering the following question. From the viewpoint of (a) the National Health Service, (b) patients and companions and (c) society, for patients with non-urgent dermatological conditions, is it preferable to provide this care in hospital outpatient departments or through a PCDS?

The analysis was based on all costs incurred over the 9 months following randomisation to either outpatient care or care in the PCDS and is reported in 2004 prices. There was some concern that resource use within the hospital arm of the trial would take place later than that within the PCDS arm because of the anticipated longer wait for treatment in the hospital arm. For this reason, resource-use data were collected for 12 months as well as for 9 months from the date of randomisation.

Physical measures of resource use are presented separately from costs. The three viewpoints are separated throughout the analysis (Coast, 2004).

6.2 Methods

6.2.1 Form of analysis

The economic evaluation was conducted in two forms. First, cost-effectiveness analyses were used to compare costs from an NHS perspective with the two primary outcomes from the trial: change in the DLQI (scored from 0 to 30 with a lower score representing a better quality of life; SD of change in DLQI for all patients, 4.49) and accessibility of care (based on three questions concerning access and scored from 0 to 100; SD of score at follow-up for all patients, 19.8). These cost-effectiveness analyses allow comparison of cost data with a single outcome. Second, a cost-consequences analysis (Coast, 2004) was used to compare costs from a number of perspectives (NHS, patient and family, and lost production to society) with both primary and secondary outcomes, where secondary outcomes additionally included patient satisfaction with the consultation, satisfaction with facilities, attendance rates and waiting times. Such presentation of data allows decision-makers to compare a broad set of outcomes with information about cost. Information about lost production is provided because the potentially different access to the two services may

impact on the time required to attend appointments, and thus the extent to which production is lost.

6.2.2 Identification of relevant costs

The costs of outpatient care and care in the PCDS were compared from the point at which patients were randomised to receive care in one of these two arms. The analysis considered the marginal cost associated with the provision of each of the treatments. Capital costs were excluded. The scope of resource use identified as being relevant was identified in conjunction with GPs and consultant dermatologists associated with the research and the provision of the two services. Costs identified as being of relevance are listed below.

Direct costs incurred by the NHS

- Initial consultation at outpatient clinic or PCDS,
- subsequent consultations at outpatient clinics or PCDS,
- inpatient admissions,
- GP consultations,
- consultations with practice nurses,
- consultations with district nurses.

Direct costs incurred by patients and their families

- Out-of-pocket expenses associated with the purchase of over-the-counter medications and the purchase of private or alternative treatments,
- travel costs,
- costs of providing care to dependants during consultations at dermatology services,
- costs associated with lost employment for those unable to obtain sick pay (including the self-employed).

Indirect costs incurred by society

- Costs of lost production associated with attendance for treatment.

6.2.3 Measurement of resource use

Much of the measurement of resource use came from computerised systems in the hospital, the PCDS and GP surgeries. Here data were collected on a per-patient basis using computerised data-collection forms.

Further information about resource use, particularly in relation to patient resource use, was derived from the questionnaires that patients were asked to complete at the time of their initial consultation at the dermatology service and 9 months after randomisation. Only costs associated with dermatology symptoms were included.

Two other sources of resource use data were also used. First, time-and-motion studies of the hospital dermatology outpatient clinic sessions were used to obtain information about the time spent with that particular group of outpatients meeting the criteria for entry to the trial. Second, nurses were asked to provide information about the consumables used during procedures undertaken in dermatology appointments, both in the hospital and at the PCDS.

NHS resource use

Consultations with the PCDS

All consultations at the PCDS are recorded by the GPs and nurse directly on to an EMIS GP computer system, and no paper records are used. This includes details of procedures, investigations, referrals and medication. Information about consultations with the PCDS was therefore obtained taken from this EMIS system at the PCDS. Each consultation was entered into the study database along with information about procedures and investigations undertaken during the consultations and medication prescribed following the consultation. Information recorded about medications included the name, dose and duration of medication.

Information about consumable resources used during procedures was collected by observation by the PCDS nurse for a sample of up to 10 patients per procedure.

Consultations with the hospital dermatology outpatients

Consultations at the hospital outpatient clinic are recorded on paper notes, but key information about procedures, investigations, referrals and medication is recorded on a data-collection sheet by clinicians and retrospectively coded on to a database at the hospital. Information about consultations undertaken at the outpatients' department was obtained from this database and the hospital's computerised appointments system. The information obtained included the number and type of investigations, the number and type of procedures and the name, dose and duration of medication prescribed.

For practical reasons, information about consumable resources used during procedures was estimated by consultation with nursing staff for the 'typical' procedure.

Primary-care and district nursing consultations

All practices in Bristol South and West PCT were visited by research staff. Details of GP and practice nurse consultations were obtained from GP computerised systems and patients' notes for all skin-related consultations. The following principles were applied to ensure that only skin-related consultations were included:

- if a skin condition was mentioned, the consultation was recorded, even if this was not the primary reason for the consultation;
- if a patient had a skin condition, but the consultation was about other problems and the skin condition was not mentioned, this was not recorded;
- if a repeat prescription was issued on the same date as a consultation (i.e. was probably issued at the consultation) but there was no mention of the skin condition at the consultation, then the consultation was not recorded (but the prescription was recorded along with other repeat prescriptions for skin problems).

The number of district nurse consultations was obtained from integrated community services system for all skin-related consultations.

Information about medication prescribed outwith the outpatient dermatology service or the PCDS was also obtained from GP computerised systems and the integrated community services system. No attempt was made to distinguish between medication prescribed for the condition for which the patient was referred and other skin problems. All prescribed items appearing in the skin chapter of the *British National Formulary* (BNF) were considered to be a relevant prescription. Where other medication was prescribed which may be used for skin problems, but may also be prescribed for other conditions, this was recorded if it was clear from the text recorded about the consultation (or the initial consultation at which the medication was prescribed, in the case of repeat prescriptions) that the item was prescribed for a skin problem. If in doubt, the item was not recorded.

Common examples of such medication included

- antihistamines for itching,
- antifungal creams, e.g. clotrimazole for fungal skin infections, but not for vaginal thrush,
- oral antibiotics for skin infections or for acne,
- the oral contraceptive pill where it was specifically prescribed for skin conditions and the records stated that it was not also prescribed for contraception, or where it was given alongside Roaccutane to prevent pregnancy while on this drug,
- oral steroids and other immunosuppressives, e.g. prednisolone for severe eczema and other skin conditions,
- bone-protecting agents, i.e. alendronic acid, disodium etidronate, and other bisphosphonates.

Information about any days of inpatient stay was obtained from BRI computerised systems. In the event there were no such stays.

Patient and companion resource use

Information about patient and companion resource use was obtained from the two questionnaires administered 6 weeks following the initial appointment and at 9 months (questionnaires 2 and 3; see Appendices 2 and 3). This included information about over-the-counter medication, use of non-NHS practitioners, travel to secondary- and primary-care appointments (including information about mileage, payments for car parking and fares), care of dependants during consultations and unpaid time off work. Information about travel, care of dependants and unpaid time off work was then linked to the appropriate consultation information taken from the computerised databases.

Societal resource use

Information about lost societal production (in the form of time taken from work) was obtained from the patient questionnaires and linked with information about the number of appointments received (obtained from the computerised databases).

6.2.4 Valuation of resource use

NHS resource use

Consultations with PCDS

Information about the time allocated to the services by the relevant practitioners and their salary costs, the administrative time and costs associated with the services and the overheads associated with the service was collected and allocated to individual patients on the basis of the annual number of patients seen within the service.

Salary costs for the nurse grade and GPs working in the service were obtained and valued, including National Insurance and pension costs (appropriate from an NHS viewpoint) and qualification costs obtained from unit costs of health and social care (Curtis and Netten, 2004; see Table 14). It was assumed that all costs for PCDS GPs could be allocated across the patients they had seen. For the nurse working on the PCDS a proportion of her time was spent on patients suitable for treatment in the PCDS, but a much larger proportion of her time was spent on direct referrals from primary care (mainly children) and district nursing. Thus only a proportion of her costs has been allocated to seeing patients from the PCDS. Further the nurse lead also spent time in leading the scheme, which has been allocated across all visits.

Costs associated with face-to-face consultation were added to the administration cost per consultation, the overhead cost per consultation and the cost associated with triaging patients for suitability for the PCDS (see Table 11) to arrive at a basic cost per consultation for consultations with the nurse and the GP (see Table 15). These administration and overhead costs were allocated across both PCDS patients seeking specialist care and those patients seen by

the nurse and referred from primary care or district nursing. A cost for the consultant time associated with triaging patients to PCDS or hospital (approx 10 hours per month) has also been allocated across PCDS patients seeking specialist care.

Table 11 Basis of valuation for consultations at PCDS

Practitioner type	Annual cost	Allocated across…	Cost per consultation
Nurse	£4982	95 consultations	£52.37
GPs	£44 187	756 consultations	£58.45
Nurse time in leading the scheme	£5981	1209 consultations	£4.95
Administration	£12 028	1209 consultations	£10.78
Overheads*	£3381	1209 consultations	£2.80
Time spent on triage of PCDS patients	£1568	1209 consultations	£1.52

**Annual overheads from the health centre allocated to the PCDS on the basis of square meterage used within the health centre (3.26%).*

Table 12 Values used for basic consultation with PCDS

Type of consultation	Cost per consultation
PCDS – surgery consultation	£78.49
Nurse – surgery consultation	£72.48

Value of initial and follow-up consultations at hospital dermatology outpatients

A value for the staff time associated with consultations at the hospital outpatients' dermatology department for trial patients was estimated from a time-and-motion study using data collected during the study. Five outpatient clinic sessions were identified. For each of these sessions a list of appointments was obtained and, during consultation with a clinical expert, the nature of each of these appointments was determined as being either suitable or unsuitable for treatment within the PCDS.[b] During the clinic, the grade of the medical staff seeing

[b] This distinction was necessary because it was recognised that some patients seen at the hospital were more complex and required different levels of care compared with those seen at the PCDS, so it was important to assess the time spent with patients who might have been transferred to the PCDS.

each patient and the time spent with them was noted. This enabled calculation of the number of minutes spent by different grades of staff with each of the patients considered suitable for treatment within the PCDS. In valuing these minutes spent with staff, the following information was used:

- information from the hospital finance department about salary, usual hours of work and holiday entitlement;
- information from *Unit costs of health and social care* (Curtis and Netten, 2004) about the time spent on patient-related activity, and information from the time-and-motion study about the proportion of the clinic time spent in face to face activity;
- information from *Unit costs of health and social care* (Curtis and Netten, 2004) about qualification costs associated with each grade of staff;
- information from *Unit costs of health and social care* (Curtis and Netten, 2004) about overheads for each grade of staff (in the absence of usable information from the hospital);
- information from the time-and-motion study about the administrative time spent on clinics.

With all this information it was possible to estimate the cost associated with a consultation of a patient appropriate for care within the PCDS. Information about the values used in the analysis is given in Table 16.

Table 16 Basis for valuation for consultations with doctors in the hospital outpatients' department

Practitioner type	Annual cost*	Proportion of face-to-face time	Minutes per consultation	Cost per minute	Average cost per consultation
Consultant	£146 625	40.3%	5.55	£3.07	£17.01
Specialist registrar	£76 486	65.6%	12.13	£1.08	£13.07
Clinical assistant	£68 750	43.0%	2.03	£1.34	£2.71
E grade nurse†	£29 180	–	14.17	£0.31	£9.35
D grade nurse†	£26 665	–	8.67	£0.28	
B grade nurse†	£16 706	–	14.33	£0.18	
A & C grade 2‡	£12 647	–	37.38	£0.13	£5.00
Total					£47.15

**Includes salary, qualifications cost and allowance for overheads.*

†Nursing time was allocated across all patients in the clinic.

‡A&C time included the cost of preparing the notes for clinic.

The cost of a nurse consultation at the hospital outpatients' department was also calculated using data collected during the clinics. Here it was assumed that only the cost attributable to the time spent by the nurse (plus overheads and qualification costs) was incurred in these consultations, giving a cost per patient of £6.44.

Values for procedures and investigations within specialist care

Costs associated with the conduct of investigations (costs from the relevant hospital departments), procedures (consumable costs valued using NHS logistics for PCDS and obtained from the hospital finance department for hospital procedures) and medication (valued using the BNF) were calculated separately for each patient. Costs associated with procedures and investigations are shown in Tables 17 and 18.

Table 13 Values used for investigations

Type of consultation	Cost per consultation
Microbiology	£13.90
Biochemistry	£2.85
Haematology	£3.00
Mycology	£22.75
Histopathology	£44.41
Patch test	£9.71
Skin-prick test	£9.71
Immunology	£15.00
Radiology	£15.00
Virology	£10.15

Table 14 Values used for procedures

Procedure	Cost	
	PCDS	Hospital
PUVA (course)	N/A	£101.97*
Excision	£16.44†	£15.80*
Punch biopsy	£15.92†	£15.80*
Curettage and cautery	£19.85†	£5.19*
Incisional biopsy	£16.44†	£15.80*
Triamcinolone acetonide injection	£1.70‡	£1.70‡
Hosiery	£2.12‡	£2.12‡

This tables excludes basic consultation costs and costs of investigations, which are calculated separately.

**Obtained from hospital finance department.*

†Calculated from nurse-provided information.

‡Taken from BNF.

Values for primary-care and district nurse consultations

Information about the costs associated with primary-care and district nurse consultations were obtained from *Unit costs of health and social care* (Curtis and Netten, 2004) on a per-surgery-consultation or -home-visit basis as appropriate (Table 19). Qualification costs are included for all staff members.

Table 15 Values used for consultations outside the dermatology services

Type of consultation	Cost per consultation
GP – surgery consultation*	£19.00
GP – home visit*	£59.00
Practice nurse – surgery vist†	£9.00
District nurse – home visit†	£20.00

**Including qualification costs; excluding direct care-staff costs.*

†Including qualification costs.

Medication

Information about costs of medication associated with consultations at the PCDS, hospital or prescribed from general practice was obtained from the BNF.

Valuation of patient and companion resource use

The majority of patient and companion resource use was valued using the patient questionnaires. This included over-the-counter medication, private health practitioners, fares, child care/care of dependants and parking charges.

Other information was obtained from a variety of sources, as follows.

- Information about mileage costs was obtained from the AA schedule and a value of 40.98 pence per mile was used (using the assumption of an annual mileage of 10 000 miles for a car costing between £10 000 and £13 000 when new).
- For unpaid absence from work mean hourly earnings (excluding overtime) for 2004 for employees in the city of Bristol were obtained from the New Earnings survey, giving a value of £11.56 per hour of work lost (Source: http://www.statistics.gov.uk/downloads/theme_labour/ASHE_2004_inc/tab8_6a.xls).

Valuation of lost production

For paid absence from work mean earnings from the New Earnings survey for the city of Bristol were used, as above.

6.2.5 Statistical analysis

Where possible, both resource-use and cost data are presented. For some items of resource (e.g. medication, methods of travel) the variety of different types means that only cost data can be presented in an interpretable way. Data are reported as means; SDs are presented for resource use only. Data were analysed using Stata software (Stata Corporation, 2005).

Dealing with missing data

NHS resource-use data were complete, but data were missing from the questionnaires which collected patient, family and lost production costs. Missing data arose from a number of sources: not attending the allocated appointment so failing to complete one of the questionnaires; withdrawal from the study; failure to complete entire questionnaires; failure to complete particular items within a questionnaire. Given that some of these reasons, particularly the first, suggest that data are not missing completely at random, data are presented both with and without imputation. Imputation of data was conducted separately for patient and family costs and for costs of lost production, based on models containing age, sex and all elements of the relevant cost category and using the multiple imputation by chained equation procedure (mvis) in Stata.

Cost-effectiveness analysis

The primary outcome measures (DLQI, access score) were combined with mean NHS costs to estimate incremental cost-effectiveness ratios. These represent the additional cost per additional DLQI point gained, and the additional cost per additional 10-point increase on the access scale. Uncertainty was represented through the use of cost-effectiveness acceptability curves obtained using bootstrapped data. These curves show the probability that the use of the PCDS service is cost-effective compared to the hospital outpatients' appointment for a range of values that the decision-maker might be willing to pay. Given that these curves are dependent on the decision-maker's willingness to pay for improved outcomes and the decision-maker's budget constraints, only NHS costs are included in these analyses.

Sensitivity analyses

The statistical analyses account for uncertainty surrounding the data collection. Sensitivity analysis was used to account for structural uncertainties of which there are two of concern. First, whether or not the longer waiting period for a hospital appointment would result in resource use within the hospital arm of the trial taking place later than that within the PCDS arm. For this reason, NHS resource-use data were also collected for 12 months from the date of randomisation and results for this extended time period are presented in the first sensitivity analysis.

Second, there was concern that the scheme was underutilised during this trial with a consequent influence on unit costs. Twenty-two per cent of appointments were unfilled; costs assuming that these appointments were filled (£60.05 for a PCDS appointment; £55.28 for a nurse appointment) were used in the second sensitivity analysis.

6.3 Results

6.3.1 NHS resource use

Consultations in specialist services

Physical resource use associated with each form of care is presented in the following tables. Details of the number of consultations in specialist services (PCDS or hospital) and in primary care are followed by details of investigations and procedures separately. Table 20 shows that the total number of specialist consultations (PCDS and hospital consultations combined) for patients in the PCDS group is slightly higher than for those in the hospital group.

Table 16 Resource use for PCDS and hospital care for 9 months following randomisation: consultations

	Mean resource use (±SD)	
	PCDS (*n*=354)	**Hospital (*n*=202)**
Hospital – doctor	0.175 (±0.551)	1.42 (±1.04)
Hospital – nurse	0.0565 (±0.2860)	0.0841 (±0.3424)
PCDS consultation – GP	1.54 (±1.29)	0
PCDS consultation – nurse	0.155 (±0.707)	0
GP – surgery consultation	0.726 (±1.521)	0.629 (±1.268)
GP – home visit	0.00282 (±0.05315)	0
Practice nurse – surgery visit	0.316 (±2.756)	0.188 (±0.989)
District nurse – home visit	0.00847 (±0.15944)	0

Primary-care and district nurse consultations

Data reported above include the outlying PCDS patient who had in excess of 50 practice nurse consultations at both 9 months and 1 year. Excluding this outlying patient reduced the number of practice nurse consultations among the PCDS group to 0.176 (±0.763) per patient at 9 months and 0.178 (±0.765) per patient at 12 months.

Investigations

Investigations were undertaken for patients in both arms of the trial. Investigations are categorised only by the arm of the trial to which the patient was randomised, and not by the service in which the investigation was undertaken, because all are costed on the same basis.

Table 17 Resource use for PCDS and hospital care for 9 months following randomisation: investigations

	Mean resource use (±SD)	
	PCDS (*n*=354)	**Hospital (*n*=202)**
Biochemistry	0.0198 (±0.1394)	0.0495 (±0.2777)
Haematology	0.107 (±0.353)	0.0396 (±0.196)
Histopathology	0.172 (±0.393)	0.109 (±0.312)
Immunology	0.00282 (±0.05315)	0.00495 (±0.07036)
Microbiology	0.00565 (±0.07506)	0.0198 (±0.1397)
Mycology	0.0226 (±0.1488)	0.0297 (±0.1702)
Patch test	0.0960 (±0.5395)	0.139 (±0.631)
Radiology	0.00847 (±0.09180)	0.00495 (±0.07036)
Skin-prick test	0.0282 (±0.1971)	0
Virology	0	0.00495 (±0.07036)

Table 18 Resource use for PCDS and hospital care for 9 months following randomisation: procedures

	Mean resource use (±SD)		
	PCDS (*n*=354)		**Hospital (*n*=202)**
	PCDS-provided	***Hospital-provided***	
PUVA (course)	0	0.0169 (±0.1836)	0.00495 (±0.07036)
Excision	0.0621 (±0.2532)	0	0.0347 (±0.1834)
Incisional biopsy	0.0339 (±0.1962)	0.0141 (±0.1182)	0.00990 (±0.09926)
Punch biopsy	0.0621 (±0.2418)	0.00282 (±0.05315)	0.0347 (±0.1834)
Curettage and cautery	0.0508 (±0.2325)	0	0.0545 (±0.2275)
Triamcinolone acetonide injection	0.0141 (±0.2190)	0	0
Hosiery	0.00565 (±0.07506)	0	0

Procedures were undertaken for patients in both arms of the trial. For patients randomised to the PCDS, procedures are categorised by whether they were undertaken in the PCDS or in the hospital, as procedures in these two locations are costed differently. All procedures for those in the hospital arm of the trial were undertaken in the hospital.

6.3.2 Patient resource use: private practitioners

Table 23 shows the number of consultations that patients in each group had for their skin problems with a range of private practitioners.

Table 19 Resource use for PCDS and hospital care for 9 months following randomisation: private practitioners

	Mean resource use (±SD)	
	PCDS (*n*=354)	**Hospital (*n*=202)**
Private doctor (*n*=202, 115)*	0.0248 (±0.1850)	0.0261 (±0.1601)
Homeopath (*n*=197, 113)	0.0406 (±0.3325)	0.00885 (±0.09407)
Acupuncturist (*n*=196, 115)	0.0204 (±0.2255)	0.0957 (±0.7720)
Herbalist (*n*=196, 114)	0.553 (±0.463)	0.0263 (±0.2087)
Reflexologist (*n*=257, 144)	0.0233 (±0.3178)	0
Aromatherapist (*n*=196, 112)	0.00510 (±0.07143)	0
Other (*n*=197, 116)	0.0102 (±0.1005)	0.0690 (±0.3665)

**Numbers relate to the number of patients providing data about this issue from the PCDS and hospital groups respectively.*

6.3.3 NHS cost per patient

Table 24 shows the results of combining NHS resource use with information on valuation, in terms of mean cost per patient. The costs associated with these consultations for patients treated by PCDS are clearly higher than for those treated in the hospital setting because both the number of consultations and cost the per consultation are higher in the PCDS.

Information about the costs of medication prescribed by the hospital or PCDS (specialist-prescribed medication) or in general practice is included in Table 20.

Adding in the costs of consultations in primary care, investigation, treatment and medication increases the difference between the two arms, and the total NHS costs associated with PCDS care are approximately 75% higher than those associated with hospital care.

Table 20 Mean NHS costs for PCDS and hospital care for 9 months following randomisation

Resource item	PCDS (*n*=354)		Hospital (*n*=202)
Consultations			
Hospital – doctor	£8.26		£66.99
Hospital – nurse	£0.36		£0.54
PCDS consultation – GP	£121.06		0
PCDS consultation – nurse	£11.26		0
Total – specialist-care consultations	£140.94		£67.53
GP – surgery consultation	£13.79		£11.95
GP – home visit	£0.05		0
Practice nurse – surgery visit	£2.85		£1.69
District nurse – home visit	£0.17		0
Total – primary-care consultations	£16.86		£13.63
Investigations			
Biochemistry	£0.06		£0.07
Haematology	£0.32		£0.12
Histopathology	£7.65		£4.84
Immunology	£0.04		£0.07
Microbiology	£0.08		£0.28
Mycology	£0.51		£0.68
Patch test	£4.27		£6.16
Radiology	£0.13		£0.07
Skin prick test	£0.27		0
Virology	0		£0.05
Total – Investigations	£13.33		£12.33
Procedures	***PCDS-provided***	***Hospital-provided***	
PUVA (course)	0	£1.73	£0.50
Excision	£1.02	0	£0.55
Incisional biopsy	£0.56	£0.22	£0.16
Punch biopsy	£0.99	£0.04	£0.55
Curettage and cautery	£1.00	0	£0.28
Triamcinolone acetonide injection	£0.02	0	0
Hosiery	£0.01	0	0
Total – treatments	£5.61		£2.04

Specialist-care medication	£22.22	£12.26
Primary-care medication	£8.95	£10.34
Total – medication	£31.17	£22.60
Total – cost to NHS	**£207.91**	**£118.13**

6.3.4 Costs to patients and their families

Table 25 shows costs associated with patient and companion resource use, as well as costs of lost production using data both with and without imputation.

Table 21 Mean costs to patient and companion and lost production costs with and without imputation for PCDS and hospital care for 9 months following randomisation

Resource item	PCDS		Hospital	
	Without imputation	**With imputation**	**Without imputation**	**With imputation**
Patient and companion costs*				
Patient travel to hospital (*n*=295, 106)	£0.53	£0.70	£3.32	£2.35
Patient travel to PCDS (*n*=271, 198)	£3.98	£3.88	0	£0.04
Patient travel to primary care (*n*=271, 198)	£0.34	£0.34	£0.55	£0.53
Companion travel (*n*=282, 143)	£0.04	£0.06	£0.23	£0.19
Over-the-counter treatments (*n*=211, 120)	£26.36	£33.65	£36.23	£38.53
Private practitioners (*n*=192, 110)	£1.00	£0.66	£0.82	£0.45
Unpaid time off work (*n*=170, 100)	£7.48	£8.92	£9.36	£9.21
Total – patient costs	**£39.73**	**£48.21**	**£50.51**	**£51.30**
Lost production*				
Associated with patient (*n*=177, 98)	£23.38	£24.55	£27.37	£29.66
Associated with companion (*n*=256, 142)	£0.59	£2.59	£2.69	£4.69
Total – lost production	**£23.97**	**£27.14**	**£30.06**	**£34.35**

**Numbers relate to PCDS and hospital respectively.*

Using both forms of estimation, patient/companion costs and costs of lost production are higher for the hospital arm of the trial, but the

difference is smaller for the imputed patient/companion costs than for the estimate made without imputation. These costs are of a lower order than those facing the NHS.

6.3.5 Cost-effectiveness analyses – an NHS perspective

Table 24, which contains cost data for all patients involved in the trial, produces total costs which are different from those produced when only those patients are included who provided a DLQI score at the 9-month follow-up or for whom an access score was available. Table 26 contains these cost and effectiveness data for the two arms of the trial as well as incremental cost-effectiveness ratios for the two primary outcomes.

Table 22 Mean cost to NHS and effectiveness information for patients for whom outcome data are available, and incremental cost-effectiveness ratios (ICERs) for PCDS over hospital care for the two primary outcome measures of DLQI and access

Primary outcome	PCDS	Hospital	Difference between PCDS and hospital	ICER for PCDS over hospital care
DLQI gain (PCDS, n=257; hospital, n=155)				
NHS costs	£224.87	£127.61	+£97.26	£540.33/1-point gain in DLQI
Effectiveness	2.54	2.36	+0.18	
Access scale (PCDS, n=266; hospital, n=125)				
NHS costs	£243.71	£140.97	+102.74	£65.61/10-point change in access scale
Effectiveness	76.13	60.47	+15.66	

Table 26 shows that neither option is dominant: for both primary outcomes, care by the PCDS is both more beneficial (albeit not necessarily markedly so on average) and more costly. The additional cost of a 1-point gain in the DLQI through use of the PCDS service is in the region of £540, whereas a gain of 10 points in the access score can be obtained for £65. Uncertainty around these estimates is represented by the cost-effectiveness acceptability curves which show the probability that PCDS care is cost-effective relative to the maximum that decision-makers might be willing to pay for these outcome gains (see Figures 4 and 5). For example, decision-makers who are willing to pay £100 for a 10-point gain in the access scale would always find PCDS care cost-effective, whereas a decision-maker willing to pay only £60 for such a gain would find PCDS care cost-effective with a probability of only 33%.

Figure 4 Cost-effectiveness acceptability curve showing the probability that PCDS care is cost-effective for a range of decision-makers' maximum willingness to pay for a 1-point gain in the DLQI (shown in £)

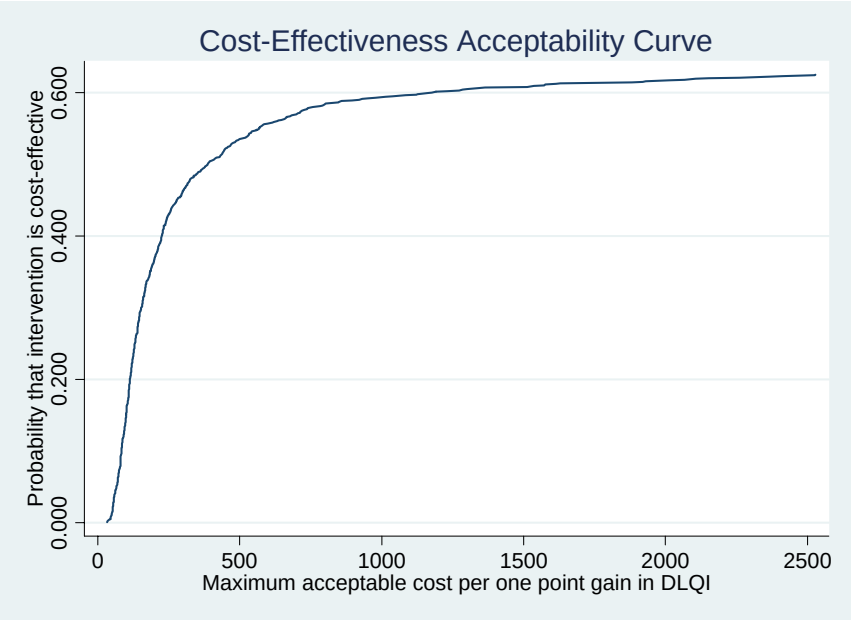
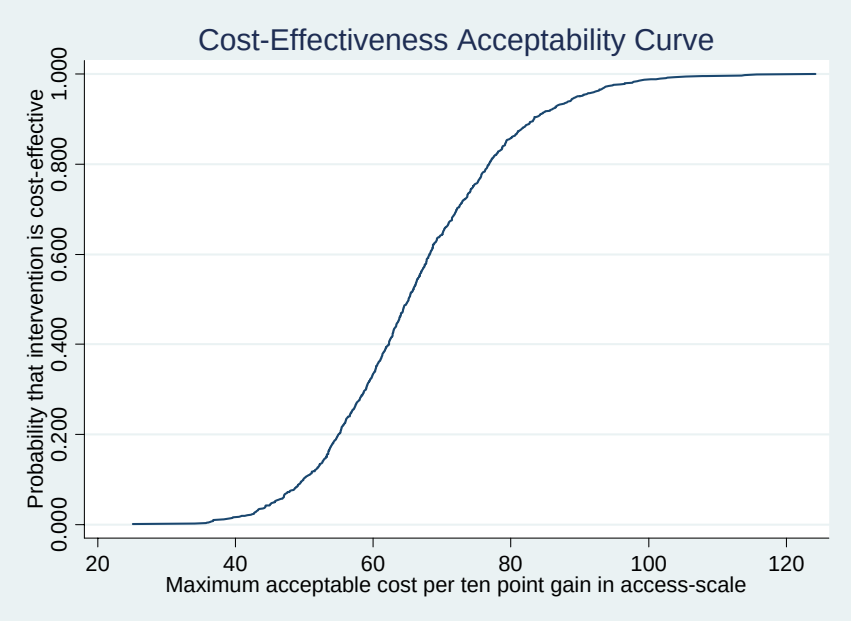


Figure 5 Cost-effectiveness acceptability curve showing the probability that PCDS care is cost-effective for a range of decision-makers' maximum willingness to pay for a 10-point gain in the access scale (shown in £)



6.3.6 Cost-consequences – a societal perspective

Table 27 provides a balance sheet summarising the costs and effects across all different perspectives and for all outcomes assessed. There is evidence of a difference between the NHS costs in the two arms of the trial, but not for patient/companion costs and costs of lost production. There are poorer outcomes for the hospital on all measures, with evidence of differences beyond chance for all except the DLQI.

Table 23 Cost consequences comparing PCDS and hospital treatment over 9 months

	PCDS	Hospital
Costs (mean, 95% CI)		
NHS costs	£207.92 (£189.51–226.32)	£118.14 (£103.15–133.13)
Costs to patients and companions	£48.21 (£32.51–63.91)*	£51.30 (£31.32–71.27)*
Societal costs of lost production	£27.14 (£8.82–45.46)*	£34.35 (£10.91–57.78)*
Outcomes (mean, 95% CI)		
Gain in DLQI	2.54 (2.00–3.08)	2.36 (1.62–3.10)
Access scale	76.13 (73.79–78.46)	60.47 (57.43–63.50)
Consultation satisfaction	71.05 (69.38–72.72)	65.93 (62.98–68.87)
Facilities scale	79.83 (78.21–81.46)	74.71 (72.04–77.38)
Waiting time (days)	72 (69.34–75.50)	113 (108.15–117.84)

**Using imputed values to allow calculation of CIs.*

6.3.7 Sensitivity analysis

For all NHS resource use for all patients the use of 12-month data resulted in a PCDS cost of £224.14 and a hospital cost of £132.91 per patient. Compared to the 9-month costs, these figures did not indicate that conducting analysis using 9-month data had adversely affected the PCDS costs.

Using a reduced cost for the PCDS to reflect possible underutilisation caused by the trial resulted in a reduced NHS cost for the PCDS arm of £176.80 per patient.

These results show that even if the PCDS operated at full capacity it would be more expensive to the NHS and to society than hospital outpatient care. In addition, this sensitivity analysis should be interpreted with caution. The time provided at the PCDS when appointments were unfilled may have been used for other necessary work such as patient administration. Furthermore, it should not be

assumed that the comparator service, the hospital outpatient clinic, was operating at full capacity despite the existence of a lengthy waiting list. The time-and-motion study demonstrated that a substantial proportion of clinicians' time was not spent in patient contact, and not all appointments were booked for a variety of reasons. If a further analysis was conducted assuming a higher patient throughput at the hospital, the cost difference in favour of the hospital would increase.

6.3.8 Summary of findings

Costs incurred by the NHS for the PCDS were approximately 75% higher than for care provided in the hospital setting. Although the number of consultations is slightly higher among PCDS patients, the major contribution to the increased costs service is the higher unit costs associated with PCDS consultations than with hospital specialist consultations. The main reason for these higher costs is that the PCDS patient always sees the relatively costly GPSI, whereas the hospital patient might see the relatively costly consultant but may also see one of the consultant team (registrar or clinical assistant) whose costs are much lower. The greater cost per patient may also reflect the longer consultations and smaller number of patients per clinic seen by the clinicians at the PCDS. Mean costs to patients and companions are slightly lower in the PCDS scheme, but the confidence intervals are very similar. Perhaps surprisingly, the travel costs of attending the PCDS or the hospital were similar. This may be due to the fact that in an urban setting, the distances that patients had to travel to either type of clinic were similar.

For the PCDS service there is a very slightly increased benefit in terms of outcome, but this is minimal. There are, however, benefits in terms of access, satisfaction, waiting and facilities in the PCDS service. The cost-effectiveness acceptability curve for the access scale suggests that a decision-maker who is willing to pay £100 for an improvement of 10 points in the access scale would always find the PCDS scheme cost-effective.

Section 7 Analysis of waiting times and demand

Information about waiting times for a first appointment was collected in the randomised trial, but further information about this issue was obtained by examining waiting times at the BRI over time compared with neighbouring trusts.

An analysis of demand for dermatology appointments, expressed as referral rates from general practitioners, made it possible to explore the possibility of induced demand, with GPs in Bristol South and West PCT increasing their referral rates because of the existence of the new service. This effect may occur because GPs became aware of a new, potentially more accessible, service, because of a perception of increased service capacity, reduced waiting times or a combination of these factors.

7.1 Aim

To evaluate impact of the PCDS on demand for outpatient referrals from primary care, and waiting times for outpatient dermatology through descriptive analysis of routine data.

7.1.1 Objectives

- To determine trends in GP referral for outpatient dermatology before, during and after recruitment to the trial of a PCDS in one PCT (the study PCT).
- To compare trends over time in GP referrals from the study PCT with neighbouring PCTs not served by the new PCDS.
- To determine trends in waiting times for dermatology outpatients at the local acute trust participating in the trial before, during and after recruitment to the trial.
- To compare waiting times for dermatology outpatients at the local acute trust with neighbouring acute trusts.

7.2 Methods

Routine outpatient data collected by local acute trusts on the Patient Administration System (PAS) is sent via the Nationwide Clearing Service to the Avon Information Management and Technology Consortium. These data cover patients registered with GPs in five PCTs: Bristol South and West, Bristol North, North Somerset, South Gloucestershire and Bath and North East Somerset.

Dermatology outpatient data for this evaluation were obtained from the Avon Information Management and Technology Consortium. The data specified for inclusion were:

- new outpatient referrals,
- specialty dermatology,
- all categories of urgency,
- aged over 16 years,
- referrals from GPs,
- patients who attended an appointment.

These data were either collected in mandatory fields in the PAS system data-set, or derived from mandatory fields.

Data were sought for the period 1 January 2001 (to include a full year before piloting of the new PCDS began) to 30 November 2004 (to include a full year from the end of recruitment to the trial). However, some of the patients referred from July 2004 onwards had not yet been seen at the time of this analysis; therefore, complete data are only available until June 2004.

7.2.1 Waiting times for new dermatology outpatients (GP referrals) at local acute trusts

Waiting times in days were calculated for each patient retrospectively, once the patient had been seen, as the total wait in days from the date the referral was received to the date actually seen in outpatients. Mean waiting times were then calculated for patients referred each month, once all patients referred that month had been seen.

Data on waiting times were available from the local acute trust and three neighbouring acute trusts providing outpatient dermatology services. These data do not include patients seen in the PCDS.

7.2.2 Demand for dermatology outpatients from local PCTs

Data on monthly referrals to dermatology outpatients for patients registered with GPs in the study PCT and three neighbouring PCTs were obtained from the Avon Information Management and Technology consortium. These included dermatology referrals (as specified above) to the local acute provider and three neighbouring providers that were seen in the hospital outpatients' department or the PCDS.

For the study PCT, patients referred to the acute trust and actually seen in the PCDS had been removed from the PAS database and recorded on a separate database at the PCDS. Data on referrals seen at the PCDS were therefore obtained separately.

Data were expressed as crude monthly referral rates per 1000 population from each PCT, using GP-registered PCT population data from the Exeter system, as of March 2003.

7.2.3 Analysis

Tests of statistical significance were not conducted for the data about waiting times and referral rates at PCT level. The small number of trusts examined, the high level of month-to-month variation and uncertainty about the reliability of these routinely collected data made statistical comparisons inappropriate. In addition, many different factors affected waiting times in different trusts during the period of this study, so it would be impossible to attribute change to the establishment of the PCDS, even if differences between Bristol South and West PCT and other neighbouring PCTs were observed.

7.3 Results

The data reported here only include GP referrals, which locally account for 87.4% of new dermatology referrals.

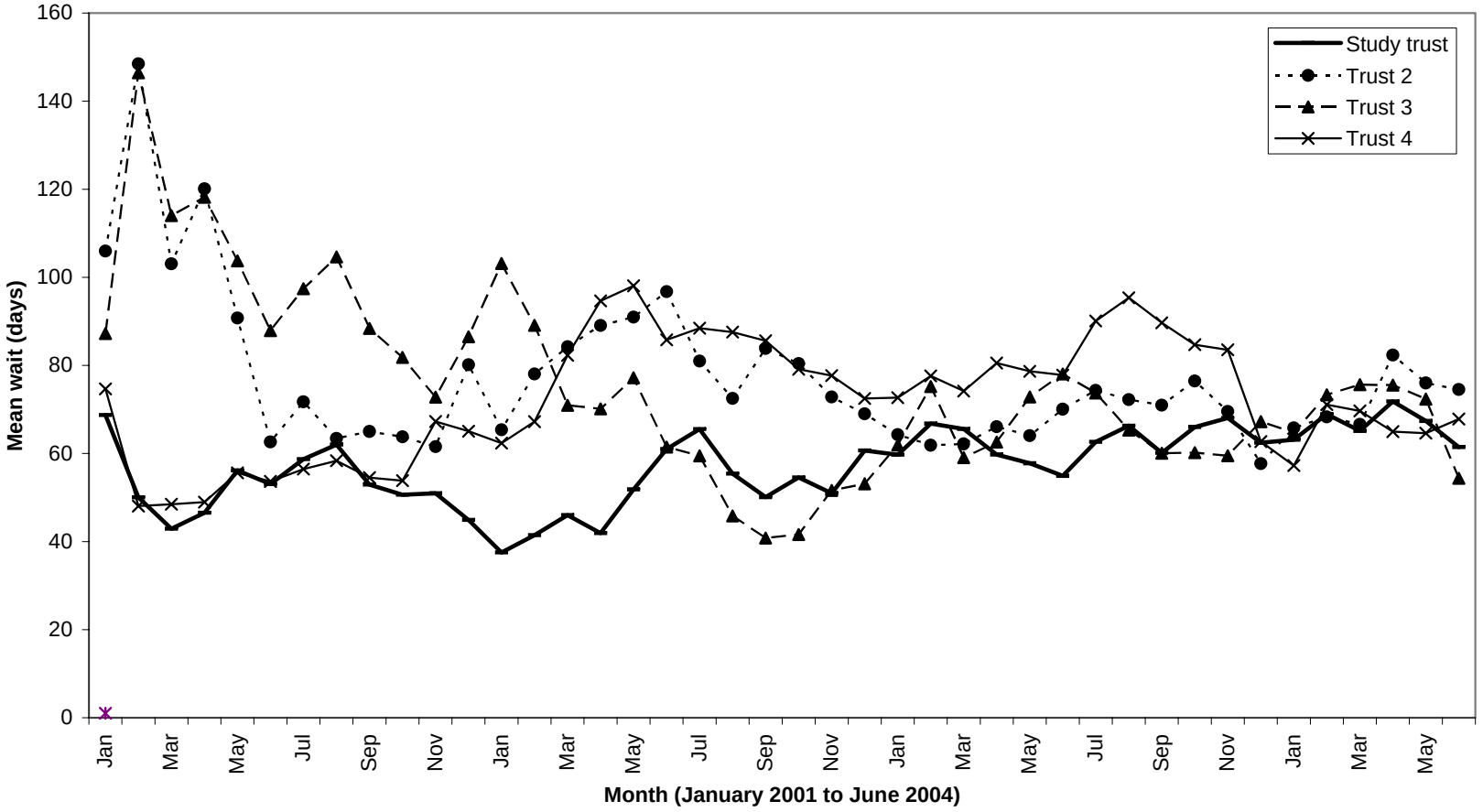
7.3.1 Mean waiting times

Data were available routinely for patients registered with Avon GPs, but it was not possible to obtain complete data for patients seen at all the four acute trusts who were registered with GPs in bordering PCTs. This is particularly relevant to acute trusts 2 and 3.

Available data on mean waiting times for adult dermatology outpatients at the local acute trust and three neighbouring acute trusts are shown in Figure 6.

Between January 2001 and June 2004 mean waits at the local acute trust varied between 38 and 72 days. Other trusts have shown greater variability in waiting times (e.g. 58–148 days in trust 2), particularly with higher waiting times during 2001. During the period under study waiting times at all four trusts have converged. Comparison of mean waiting times for January–June 2001 with January–June 2004 show a mixed picture across the trusts: the two trusts with lower initial waiting times (local trust and trust 4) had increased mean waiting times in the first half of 2004 by 14 and 13 days compared with 2001. In comparison, trusts 2 and 3 had higher mean waiting times in the first half of 2001, but mean waits were 29 and 40 days shorter, respectively, in the comparable period of 2004. However, as noted above, patients from PCTs bordering Avon are not included in these data.

Figure 6 Mean waiting times for adult dermatology outpatients (GP referrals, excluding those seen in PCDS)



7.3.2 Demand for dermatology outpatients from local PCTs

Referral rates from local GPs to dermatology outpatients are shown in Figure 7, expressed as crude rates per 1000 population overall. In the study PCT the monthly number of referrals ranged from 95 to 298. Overall trends across the time period studied suggest a small upward trend in the study PCT. Comparison of referrals during the first half of 2001 with the same months of 2004 showed a rise of 22% in GP referrals in the study PCT; neighbouring PCTs showed increases of 0, 9 and 16%. Overall across the four PCTs the growth in first half-year referral numbers between 2001 and 2004 was 13%.

The available data suggest demand has risen overall, with a greater increase in the study PCT than neighbouring PCTs.

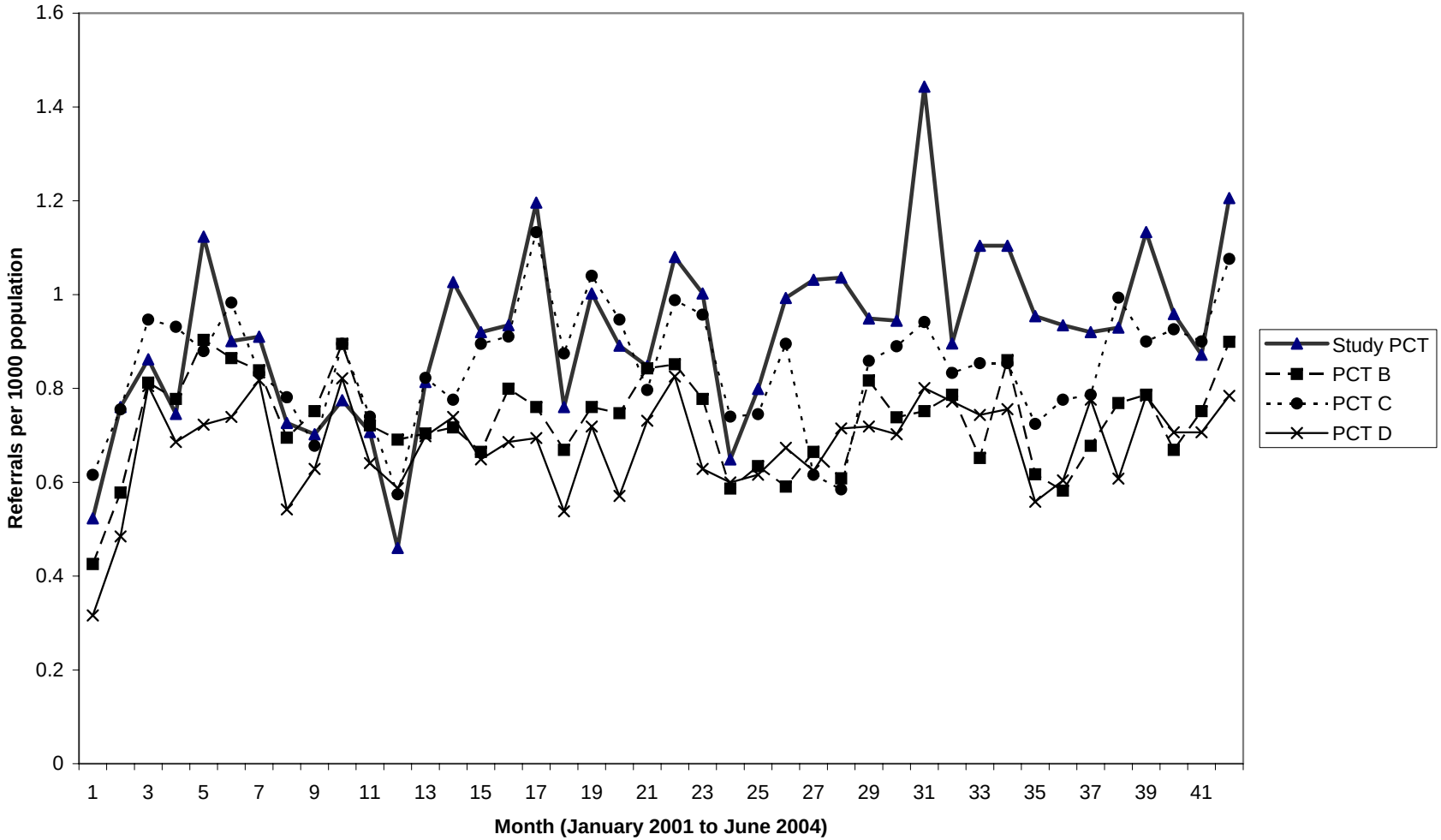
7.3.3 Commentary

To put these findings in context, it should be noted that the new PCDS was available to GPs in one PCT only, and while this PCT was the main source of outpatient dermatology referrals to the local acute trust, four other PCTs referred to that trust, and from 2001 data these together made up half the overall GP referrals for outpatient dermatology at the local acute trust. This will therefore limit the impact of new PCDSs in the study PCT on the local acute trust dermatology service overall. Referral data suggest that in 2003 less than a quarter of the total GP referrals to dermatology from the study PCT were seen at the PCDS.

The total number of patients referred and seen at the BRI dermatology department between 1 September 2002 and 30 October 2003 was 5419, with referrals from GPs in Bristol South and West PCT representing 2473 of these. The total number of referrals transferred to the GPSIs at the PCDS during the same period was 414 (these figures are greater than the number of patients in the trial because they include patients referred before the trial began, and patients referred from other PCT areas). Therefore the PCDS represents an extra capacity of only 8% (414/5419).

Another way of looking at this issue is in terms of total appointments. The total number of consultations with doctors at the PCDS in the period 1 September 2002 and 30 October 2003 was 882, and the number of appointments at the BRI dermatology department was 11 248, so the PCDS provided an extra 7.8% (882/11 248) of appointments. This relatively small increase in total capacity makes it unlikely that the establishment of the PCDS would have a substantial impact on average waiting times at the BRI.

Figure 7 Outpatient dermatology referral rates by PCT (including patients seen in study PCT PCDS)



It is also important to bear in mind that the PCDS represents an 'intervention' in the study PCT, but it cannot be assumed that the other trusts in this study were not also introducing other interventions in the same period. All trusts were under pressure to reduce outpatient waiting times during this period and were reacting to NHS targets, and they will have introduced different measures to achieve this. The convergence with regard to waiting times is consistent with the impact of such targets. This raises the question of which interventions are the most cost-effective means of reducing waiting times, which cannot be answered directly from this research but is considered in more depth in the Discussion (Section 10).

Section 8 Qualitative study

8.1 Aim

It is proposed to expand specialist services taking place in primary-care settings so that by 2006 10% of all outpatient appointments will take place in the community (Department of Health, 2000). However to date little is known about UK dermatology patient attitudes to proposed variations in secondary-care service delivery or the values they attach to aspects of the care they receive. Some studies, conducted with non-UK patients, have reported improved satisfaction where patients felt their doctor empathised with the problems they faced regardless of the degree of clinical severity. Although many people were confident in the care offered by a primary-care provider, they reported greater confidence in care provided by a dermatologist (Federman *et al.*, 2001; Collins *et al*., 2004).

This section reports the findings of a qualitative study carried out to address two aims: first, to identify and explore the aspects of care patients with skin conditions deemed important in making choices about service use; and second, to inform and develop the attributes and levels for a discrete-choice experiment questionnaire to survey dermatology outpatients about their preferences for care.

8.2 Methods

The purpose of this study was to seek and explore the experiences, understandings and values attached by people with skin complaints to the health services available to them, and for this reason qualitative methodology is appropriate (Bowling, 1997). Following the end of recruitment to the main trial, patients over the age of 16 years with skin complaints suitable for inclusion, i.e. new referrals requiring routine outpatients' appointments, were purposefully sampled for interview on the basis of obtaining a range of patients in terms of age, gender, presenting conditions and proximity to the service. GP referral letters to the BRI dermatology outpatients' department were examined to obtain a sample of patients with both acute and chronic skin complaints. As one of the aims of the study was to examine the acceptability of the PCDS compared to consultant outpatients' care, only patients who were suitable for the PCDS but were seen in either setting were included. Information about the study and an invitation to be interviewed were sent to patients with their appointment letter. Those patients who expressed an interest and gave their personal details by telephone or letter were then contacted by the researcher (SH) to arrange an interview at their convenience. Since patients' expectations might have been coloured by previous experience of dermatology services some interviews took place before and some after treatment to obtain as diverse views and experiences as

possible. Patients gave written consent for interviews, which were taped and transcribed.

Semi-structured interviews were conducted using an interview schedule, although participants were encouraged to explore their own priorities for care in the course of the interview (Appendix 9). Topics for inclusion in the initial schedule were identified by literature review and examination of patient comments about reasons for refusal to participate on the randomised-controlled-trial consent forms. Analysis of these consent forms showed that issues relating to convenience such as distance, availability of public transport and local perception of the PCDS location, in addition to expressed preferences to receive consultant-led care, were the reasons most frequently cited for not participating in the main trial. The initial interview schedule also included patient history and experiences of obtaining care for their skin complaint, waiting time for the outpatients' appointment and preferences for specialist care. Specific questions to confirm understandings of identified concepts related to preferences for care were included towards the end of the interviewing phase.

8.2.1 Analysis

Interviews were transcribed and coded using ATLAS-ti, a software package designed to assist in organisation of data for qualitative studies. An iterative approach to analysis was used, with initial coding and analysis proceeding during the course of interviewing and informing the sampling strategy. Reliability of coding was assessed by the first interviews being read and coded by SH, then by another researcher (JC), and compared. Initial coding was then organised into categories that illustrated the interplay of factors emerging from the interviews. Disconfirming accounts were actively sought as this is known to strengthen the analysis (Gilchrist, 1992). To explore any possible relationship between the nature and severity of the skin complaint and participants' views on the acceptability of the PCDS, patients' experiences of the severity of the presenting skin complaint were coded.

Further details of the iterations by which the factors of importance to patients to be included in the discrete-choice modelling study emerged are described in Section 9.

8.3 Results

Twenty interviews were carried out – all except one took place in the patients' homes and lasted between 30 and 90 minutes. In two cases the participants' spouse contributed to the interview.

8.3.1 Participants

Nine participants lived either in or around the main urban centre where the hospital dermatology outpatients' department was situated.

The remainder lived between 9 and 20 miles away. At the time of their interviews 14 had already attended their appointment at either location, while one had taken the option of private treatment due to the wait anticipated by her GP. Five patients were awaiting their first appointment. Table 28 shows the participants and their skin complaints. A quarter of the participants had undiagnosed skin lesions.

Table 24 Participants in qualitative study, their skin complaint and location of care

Participant	Age	Sex	Diagnosis	Location of care	Own transport?	Comment
1	83	F	Urticaria angio-oedema	PCDS	N	
2	20	M	Undiagnosed	Hospital*	N	Offered PCDS and refused
3	73	M	Bowen's disease	PCDS	Y	
4	47	M	Psoriasis	Hospital	Y	Offered PCDS and refused
5	72	M	Infected nail	PCDS	Y	
6	33	F	Undiagnosed mole	PCDS*	Y	
7	32	F	Alopecia	Private	Y	Offered PCDS too late
8	75	M	Solar keratoses	PCDS	Y	
9	45	M	Wart on eyelid	PCDS	Y	
10	43	F	Eczema	Hospital*	Y	
11	51	M	Psoriasis	Hospital	Y	
12	83	F	Bowen's Disease	PCDS	Y	
13	31	F	Contact dermatitis	PCDS*	Y	
14	73	F	Solar keratoses	PCDS	Y	
15	83	M	Undiagnosed	PCDS*	Y	
16	56	M	Undiagnosed	Hospital	Y	
17	66	M	Undiagnosed	Hospital	Y	
18	53	F	Psoriasis	Hospital	Y	Would have paid for private treatment if appointment not offered quickly

19	47	F	Urticaria	Hospital	Y
20	47	F	Solar keratosis	Hospital	Y

**Not yet attended their appointment.*

Participants presented with a range of minor skin complaints ranging in severity from painless but undiagnosed skin lesions that may or may not have significance for long-term health to chronic conditions such as psoriasis and eczema with significant effects on the individuals' quality of life. Although patients had been referred by their GPs for non-urgent outpatients' appointments for their skin complaint, a minority of participants expressed considerable and long-standing distress or pain arising from their skin complaint.

> *I've always been quite worried about it but when it started … at the end of the pregnancy, just after I had him, I noticed I got sort of a couple of clumps missing under here. I started to panic a bit then.*
>
> (Participant 7, female, alopecia)

> *Sometimes I can't sleep because of the itching and I have to get up and just soak them in ice-cold water just to stop that irritation, … and I will use anything on them to stop the scratching then, stop the itching which is not good, I know, but you know I get a pumice stone on there, I've used a comb, my teeth, anything that's sharp, a dry old towel which I know is not going to do them any good, I know it's going to make them worse but it's just the itching…*
>
> (Participant 13, female, contact dermatitis)

Participant 11 had been affected by increasingly severe psoriasis since his teens and at the time of his referral was spending over an hour a day applying creams. Self-consciousness about his condition led him to choose clothing to minimise the possibility of inadvertently exposing even his arms at work.

> *You know, when there is warm weather I can't wear shorts or shirts with short sleeves I have to keep covered up because of embarrassment …('you get depressed' – wife). Get depressed. Can't go swimming, I'd love to go swimming but I can't do any of those things. I work with the public and sometimes it affects areas that I can't cover up and then it gets embarrassing.*
>
> (Participant 11, male, psoriasis)

8.3.2 Themes

The acceptability of a local dermatology service was influenced by four inter-related themes that emerged from the interviews: participants' perception of their need (urgency) for diagnosis or treatment, which influenced their willingness to wait for an appointment, their experience of primary-care services, their perception of what constitutes specialist expertise and factors relating to the convenience of the respective services.

Need for treatment

Perceptions of the level of service provision and need for access appeared to be markedly different between participants. Some participants expressed surprise that what seemed to them to be a relatively minor problem could not be managed by their own GP. Participant 3, for example, had self-diagnosed his skin complaint from previous experience of the same condition. He was frustrated that the particular creams he had been prescribed for the first episode did not seem to be available from his local surgery and that he had to be referred to the hospital for the same treatment.

P3: In fact it seems such a small thing, having had the same treatment on my two things now, I could diagnose it myself now, something like that…I mean I don't know why the doctor couldn't have said 'well it looks like you have had this before, it looks like the same thing.'

S: Your own GP?

P3: Yes, my own GP. Presumably it is on my notes what happened last time and what the treatment was. It did seem, why am I having to wait this length of time to go and see someone, when I know what the treatment will be (and indeed it was)! So why have I got to see a real specialist? Couldn't my doctor have done it?

(Participant 3, male, Bowen's disease)

Other participants expressed similar irritation. One man having received sutures for a head injury in his GP surgery felt that there was little difference between that procedure and the one he now required.

I can't see why this, I HONESTLY cannot see why that (gesturing with his finger) couldn't, MY doctor, they have a perfectly good surgery in B. I can't see why they can't say, 'right Mr G., come in next week; we're going to inject there, we're going to cut there', can't do it! I can't honestly see why it can't be done.

(Participant 5, male, chronic infection of the nail bed)

Another expressed disappointment that an unsightly wart on his eyelid could not be treated at his local surgery.

…initially I was quite hopeful that they would actually be able to do something at my local doctors'. So I suppose when he said 'I need to refer you', I guess I was a little bit disappointed.

(Participant 9, male, wart on eyelid)

Participants were aware of the potential significance of skin lesions and this instigated a sense of urgency for diagnosis and treatment.

It was a sore on my nose which I knew I hadn't done anything, I hadn't knocked it or anything, and it didn't heal up and I'm also very, well for decades, very conscious of melanoma and I thought 'Aghhhhhh' you know, so that was what took me in the first place. I knew it was unusual and it wasn't just something, you know, because it went on for longer than it should have done – it wasn't healing.

(Participant 20, female, solar keratosis)

S: How worried are you about them?

> *P14: Quite worried actually, well, because I always think of my mum with her face suddenly, um you know, and I had a friend who had a thing grow on the top of her hand. Well it only started off as one of these marks and then suddenly it started growing a crust on it, which is very similar to that one (points to arm) and that turned out to be a cancer. It's only about 5 or 6 months ago that she had that.*
>
> (Participant 14, female, solar keratosis)

Despite their own anxiety these participants were happy to wait for 4–8 weeks for their appointments, having been reassured by their GP that their lesion was not urgent.

> *I guess if the GP had thought, oh this is serious it would have, things would have been faster. So while the GP didn't say what it was, I suppose I felt reassured that because I thought… if she'd looked at it and thought 'this is definitely a melanoma,' then I would be seen a lot quicker, I'm sure. In a way, I was reassured and I didn't mind the wait in that sense, although I wanted it healed up really.*
>
> (Participant 20, female, solar keratosis)

Those participants who recognised the relatively minor character of their complaint expressed no reservations about attending a PCDS for diagnosis and treatment, accepting that a doctor with appropriate expertise in dermatology would offer an appropriate service. They drew a distinction between their acceptance in these circumstances and the need to seek consultant care for something more major or life threatening.

> *I am not bothered where I am seen particularly. If I had a life-threatening illness I would probably feel that I would want to be seen by a consultant in a hospital.*
>
> (Participant 6, female, undiagnosed lesion)
>
> *If you're talking about something terminal or something that is very, very serious – an illness, then fine, but when you're talking about a condition which is going to be on-going, then I think it's a different kettle of fish.*
>
> (Participant 10, female, eczema)

For the majority of people interviewed a shorter waiting time for their appointment combined with a satisfactory level of expertise for treatment of their condition made the PCDS an attractive service, especially if they had already been waiting for referral or an appointment for some time.

Experience of primary-care services

Lack of satisfaction with skin consultations with their GP could have implications for the readiness with which patients would accept an appointment with a GPSI. Participants frequently reflected on their consultations with their GP and commented on the process of obtaining a referral to secondary care. Interestingly, several participants commented that their referral was actually made not by their usual GP, but by another in the same practice or a locum. Participants requiring a diagnosis for a visible, undiagnosed lesion

seldom reported any problems with obtaining a referral for an outpatient appointment. This was not the experience of participants with long-standing and sometimes painful conditions affecting the quality of their lives, and for whom, despite repeated consultations, the GP had not been able to prescribe effective treatments.

> *Way back she said to me 'I wonder if I should refer you to Dr K. because I work at the (hospital) on Thursday' and she said 'would you like me to do that?' And I said 'I would have liked you to do that a long time ago,' you know. So she said she would get on with that. And then I saw her 2 months after that and I said 'you realize that it's almost 2 years now,' and she said 'yes I've got your notes here and I can see.'*
>
> (Participant 1, female, urticaria angio-oedema)

Another participant described how he had first consulted 2 years previously with a painful condition.

> *I suppose 2 years, 2 years approximately ago. It was like – I put up with it for about 3 or 4 weeks – it was like a sunburn. The only way I could describe it was a sunburn, a very bad sunburn. You could hardly put a pair of trousers on. You know what it is when you've got a sunburn across your back and someone taps you on the shoulder, it's painful.*
>
> (Participant 17 male, undiagnosed)

After months of prescribed creams and advice about washing and clothing had made no difference to the participant's pain it was he who instigated the referral for a specialist appointment.

> *S: So your referral to outpatients, was that the doctor's idea or was that something …*
>
> *P17: No, I did … I was getting a bit fed up because I didn't want to be disrespectful to the doctor and saying 'I don't think you've hit anything that will cure me.'*
>
> (Participant 17, male undiagnosed)

It was a common experience for patients with chronic skin complaints to consult their GPs over a number of months before referral was suggested, and in many instances it was the patient who instigated the referral rather than the GP. In some cases participants felt their GP actually represented a barrier to referral. Having consulted frequently with little effect, participant 4 had questioned whether his GP had financial motives for not offering to refer him for a second opinion,

> *So maybe 6 months ago I went to the GP and I asked, well I said, 'look nothing is happening, how about referring me?' And I understand there was some reluctance to do that because the practice has to pay for a referral. Is that right? I particularly liked him, I think he is the most sympathetic in the practice and I said 'it is me again, still no joy' and he was about to offer more of the same and I said 'well I wondered about taking this a step further, and maybe going to see a dermatologist.' I mean it is not his face fell, but he – put it another way- he might have suggested it himself, and maybe he was about to – and I got in there first. But I don't think so. I think he was all for writing me*

out another prescription as opposed to OK, I can't do anything – I know someone who can.

(Participant 4, male, psoriasis)

Well, it takes a long time to be referred and often badgering, and I hate badgering the GP. And I don't think one should actually have to badger a GP for something because it makes me feel, I don't know, a bit grubby having to badger them.

(Participant 10, female, eczema)

The experience of having repeated, failed treatments in the context of consultations with their GP may have a bearing on patients' perceptions of the desirability of an alternative dermatology service run by GPs albeit with expertise in dermatology. Participant 1 accepted her appointment at PCDS because she was desperate for an expert opinion (she equated specialist service with consultant service), but expressed satisfaction with the care she had received. However, when asked if she could choose where she went next time, she emphatically chose to see a hospital consultant. Moreover, two participants refused the offer of the PCDS despite an earlier appointment, because they wanted to see an expert, someone with expertise beyond that they perceived to be possessed by the GP, both having been unsuccessfully treated by the GP for their complaint (participants 2 and 4).

Specialist expertise

There was considerable variation in the way the term specialist was understood. Whereas all participants were hoping to be seen by a specialist for their referral, they did not all mean the same thing by specialist care. Specialist care was equated with increased expertise in a particular field, not necessarily linked to an explicit title or grade of staff, with some participants trusting that if they were referred to a specialist by their GP, they would see an expert in the field, regardless of title. Some participants were content to be seen by either a member of either medical or nursing staff if they were skilled in that particular specialism, the most important determinant of care for them being timely access.

Well, I mean if you've got, you can get sort of nurses that specialise in certain… I wouldn't expect it to be somebody who's, you know, qualified over and above a GP or a doctor, as long as they specialised in the field… but, it wouldn't bother me who I was seeing or what level I was seeing as long as they knew, you know, as long as they were trained in that area.

(Participant 7, female, alopecia)

I was just glad that someone could see me sooner than I first thought or was first led to believe and that was all a plus or positive to me.

(Participant 9 male, wart on eyelid)

Participants who perceived their skin complaint to be non-urgent and of a minor nature were happy to be treated by a practitioner with the relevant training and experience regardless of title in a primary-care setting.

As long as the person gives me the right treatment I don't care if the dustman gives it me. If he has been told what to do and it is right, it doesn't matter.

(Participant 3, male, Bowen's disease)

As long as they are someone who knows what they are talking about. It's like taking the car in isn't it – if he knows what he's talking about, you've got confidence, oh he knows what he's talking about. Doctor didn't need to have a suit on or anything, I don't care.

(Participant 5, male, infected nail bed)

Participants rarely made a distinction about the relative expertise of doctors, especially hospital doctors. Hospital specialists were perceived to offer high-quality care, offering hope of a diagnosis and effective treatment, awareness of research and new therapies, instilling confidence and reassurance. For some the hospital setting was important. Participants used terms such as 'top man' (3 and 4), and 'boss' (19) to describe consultant dermatologists in hospital outpatients. Seeing the consultant was particularly important for participants who had had repeated and unsuccessful treatments in primary care. These participants' comments revealed a lack of confidence that a GP with specialist interest in dermatology would have sufficient skill and experience to manage conditions similar to their own, with implications for the acceptability of a primary-care-based service.

I need the specialist doctor. The GP, you know he told me, before I am coming, but he don't help me.

(Participant 2, male, undiagnosed)

I think in this case, because I've seen a GP who'd not (pause) unlocked the riddle, not helped me, so I thought well. And this consultant was described by the GP, you know he's your man. So he was described as the man to see, devoted his life, as opposed to someone who has may be done some training. …I guess you are looking for some confidence in dealing with a problem like this, and some hope.

(Participant 4, male, psoriasis)

P17: With someone who's got a visible skin complaint it must be easy to handle rather than what I'm trying to tell the doctor that the pain is so unbearable that I can't take it any more.

S: But do you think that, um, the complexity of the problem that you're describing would be beyond what a specialist GP could do?

P17: I don't think he would pick it up…

(Participant 17, male, undiagnosed)

I would want to be seen by someone who was a specialist. Who had extensive experience and, and, and would know about the sort of conditions. So that's the whole point and I see the GP as a filtering service… If I'm going to be referred then I'd want to be sure it's to someone who was a specialist and not someone who knew a little bit more than the next doctor.

(Participant 16, male, undiagnosed)

Participants were probed about aspects of their consultation with a hospital specialist they particularly valued. Interestingly, even when some participants reported a cursory examination or limited communication, these shortcomings were justified on the basis that the expert's very knowledge and experience negated the need for attention to these aspects of care to provide effective diagnosis and treatment.

> *I think I mean the GP had a better look than the fellow I was referred to, but then he spends his whole time doing it, so I didn't feel, hmm, that was a bit glib, because I accept he knows what he is looking at from a distance of 6 feet. He should know what he is looking at.*
>
> (Participant 4, male, psoriasis)

> *I mean I took a photograph when I had a very bad attack and I took the camera with me and I said to her, the woman, would you – shall I show you this photograph and I thought well actually no, suddenly it melted away – it's a silly idea because I thought she knows exactly what I'm talking about because she's seen hundreds of people probably with it and I didn't feel offended but some people might have, they've gone to the trouble of taking the photograph and remembering to bring it with them and actually probably I should have…. She should probably should have looked at it just to humour me.*
>
> (Participant 19, female, urticaria)

Participants who chose to attend the PDCS described a great deal of satisfaction with the individualised care they received from the doctor they saw. For some, even with an expressed preference for consultant care, those who attended PCDS reported a high level of satisfaction with the care received.

> *I would have liked to see a consultant but I felt that, um, she (GPSI) had the real interest in it where I have never felt that with the clinic that I go to.*
>
> (Participant 1, female, urticaria angio-oedema)

Convenience

Participants' comments regarding access to health services related to perceived ease of access of location (journey length, time, ease of public transport links or parking), time saving, cost, other local facilities and flexibility of appointments systems. Whereas for the most part participants thought the provision of services locally was a good idea in principle, for some a central location was more convenient as they worked or lived near the city centre,

> *[PCDS] for me would be difficult, that is the only trouble with that. Because, I'd have to borrow a car for the day, blah blah. So because I work in the centre a central place is fine.*
>
> (Participant 4, male, employed)

> *When I go to the hospital I go straight down the G (shopping centre car park) pay a couple of quid. I walk up the road, walk in, walk down and then I do a bit of shopping to save time and I know the car is going to be fairly safe.*

(Participant 5, male, retired, drives a Jaguar car)

S: So for you the hospital is more convenient?

P2: And cheaper.

S: Than catching the bus.

(Participant 2, male, refugee, lives in the inner city, no transport)

I suppose the whole thing is encompassed by time, all that. However, it is quite nice to go to B (town) and have a little mince round the shops before and after the appointment! So there are advantages to going to the centre.

(Participant 6, female, employed, lives in a rural location)

The majority of participants found a local centre to be acceptable for reasons of avoiding some perceived disadvantages of a central location such as the problems with parking necessitating use of public transport and long waits for their appointment once they had arrived. When asked about preferences for local provision of care participants equated this with their own locality. Services provided locally in a primary-care setting are generally only local to residents of that particular area. In some cases participants expressed surprise at the low-tech surroundings of a primary-care setting, equating it with a nursery or library in two cases, at odds with the professionalism of the care they received and the satisfaction they expressed.

Section 9 Discrete-choice modelling

9.1 Aim

This aspect of the dermatology project had two broad aims: to identify important issues concerning access to dermatology services; and to quantify preferences for different aspects of access to these services. The first aim was met using the qualitative work exploring access to dermatology services, discussed in Section 8. The second was met through a discrete-choice experiment.

9.2 Qualitative work

The qualitative work formed an essential stage of the design of the discrete-choice experiment. Prior to the development of the survey questionnaire, decisions had to be made about the attributes of interest and the appropriate levels of those attributes to include in the experiment. It was important that these attributes were those that are important to patients with levels that were both realistic in terms of the development of policy and capable of being traded (Ryan and Farrar, 2000). The development of both attributes and levels was conducted using qualitative work. This ensured that the attributes chosen were relevant and grounded in patients' experiences.

The methods and findings for this qualitative work have been described in Section 8. However the same data were used to inform the discrete-choice modelling study. Because the focus of the analysis was different, the methods and results are presented below, even though there is some overlap with the findings described in the previous section.

9.2.1 Design and sampling

An initial decision was taken that attributes would be explored with those patients referred to dermatology services whose skin complaint had been determined by a dermatology consultant to be appropriate for treatment within the new service. Patients were chosen rather than doctors or other service providers, because the purpose of the discrete-choice modelling was to elicit patient preferences for services. Talking to service providers rather than patients could have led to the omission of important aspects of access of which the former might not be aware.

A second decision concerned whether to use focus groups or interviews. There are advantages to both: focus groups may enable new topics to emerge in cross-discussion among informants, but interviews allow topics to be pursued in greater depth and topics that are personal to informants to be discussed in a sensitive manner.

Because of the sensitive nature of some informants' skin conditions, it was decided to use interviews here.

9.2.2 Iteration 1: early exploratory work

Methods

The first iteration of the qualitative work involved data collection through semi-structured interviews with patients (sampled as outlined in Section 8) conducted in the interviewee's home (except in one case). A topic guide was used to ensure that the same broad topics were covered with all early informants, but also allowing the flexibility for informants to introduce issues of importance to themselves. The initial topic guide was informed by both review of the literature on preferences for access and analysis of the consent forms where non-consenters had given reasons for their decision not to participate in the wider randomised controlled trial. Topics included: informants' experience of their skin condition; their knowledge of the available treatments and effectiveness; sources of help and their use; and the acceptability and accessibility of health services, including aspects such as length of wait, location and practitioner.

Early exploratory analysis used constant-comparison and grounded theory techniques in which new data are compared, initially with previous data and then with the properties of emerging categories (Glaser and Strauss, 1967; Strauss and Corbin, 1990). An hierarchical coding schedule was drawn up and a descriptive account was developed by JC using Microsoft Word for the first four interviews for which transcripts were available (patients 1, 2, 4 and 5).

Findings from iteration 1

Although the focus of the interviews had been on access to treatment it was clear from the early exploratory analysis that the overriding concern of all informants was the resolution of their skin problem. Two factors clearly emerged as important to informants in achieving the maximum potential for resolution: the knowledge and experience of the specialist they would see, and the length of time they would have to wait before they were seen. These informants showed a clear preference for expertise and experience:

> *P4: … my inclination is to go the person with the greatest knowledge.*

Frequently the preference for expertise and experience was equated with such terms as specialist, dermatologist and consultant, and the label GP was, as often, equated with the absence of this characteristic:

> *P1: …It turns out that Dr X [GP], you know, good as what she might be, she's just doing a course at (the hospital) with Dr Y [consultant] … I thought 'at last I'm going to see a dermatologist' but of course I didn't.*
>
> *P4: … because I've seen a GP who'd not unlocked the riddle, not helped me, so I thought 'well'. And this consultant was described by the GP, you know 'he's your man'…*

All informants were concerned about the length of time they would have to wait for an appointment and thus the chance to resolve their skin problem:

> *P2: For appointment I wait a long time, long time. It is coming more black, more black.*

> *P5: I mean I been reading the paper today about the waiting lists. And I thought 'Why?'… I just don't understand why we have to wait. Months and months and months.*

Other factors which emerged as important to some informants at this stage were: the willingness of the doctor to spend time with the patient; issues of physical access, such as ease of public transport or car parking; the location of the clinic in relation to other facilities; the facilities at the clinic; time spent waiting at the appointment; and the cost associated with getting to the appointment.

Importantly, from the viewpoint of conducting the discrete-choice experiment there were clear trade-offs among informants between expertise, waiting and convenience.

> *P4: …And I thought well, it is only a couple of weeks away and this doctor is meant to be the one to see so I will stick with that appointment… Maybe if it had been a 6-month wait I'd have probably gone to the other one.*

> *P1: …I would have had it anywhere. I would have gone anywhere, yes. I would have gone anywhere, absolutely anywhere, wouldn't have mattered where they made it.*

> *P4: … I guess there is a feeling you go to the big place and then you get the top consultant… But yeah I like the idea of smaller places, smaller more localised ones.*

Conclusions from iteration 1 and issues to pursue in iteration 2

From iteration 1 it seemed clear that expertise and waiting should be attributes within the discrete-choice experiment, although further interviews would need to continue to probe the relative importance of these attributes given that this early analysis was based on only four informants. It was also anticipated that the second iteration of this work would move on to the next stage of clarifying these attributes by finding out about plausible or 'realistic' levels. This presented a dilemma in relation to expertise, given that some informants (particularly informants with chronic skin conditions who had struggled to obtain a referral) were very negative about the label GP and would not necessarily distinguish an ordinary GP from a GPSI in dermatology. It was also felt to be difficult to isolate expertise from other characteristics associated with specific practitioners if these labels were used. It was therefore decided to explore the possibility of alternative ways of capturing the attribute of expertise during the second stage of the work.

Further interviews were clearly needed to continue to explore the other factors which also appeared to influence informants' preferences.

9.2.3 Iteration 2: further exploration and some confirmation

Methods

A further 11 interviews were conducted using the same basic data-collection method as already outlined. All data from these interviews and the first four (15 in total) were entered into Atlas-ti and coded. This enabled data relating to specific themes to be easily collated so as to examine both the frequency with which they arose and the relative importance to the informant. At the same time, a number of other steps were being taken to determine the levels of waiting time and expertise that would be realistic for use in the discrete-choice experiment. Data on referral waiting times from within the randomised controlled trial were examined, as were NHS policies on waiting times. The length and depth of training of different types of specialist were explored as a means of distinguishing between different levels of expertise.

Findings

The first iteration had identified the willingness of the doctor to spend time with the patient as potentially important in influencing preferences. This concept (described here as individualised care for shorthand) was identified in around half the interviews with various terms used to describe this form of care:

> *P8: …she was* very thorough*… within a few minutes I was being attended to…* I wasn't rushed *out of the door…*
>
> *P10: … somebody's actually* paying attention*…*
>
> *P14: No rush, no.* She listened to me*… and she went all over it…*
>
> *P15: I'd sooner have something which is a* bit more personal *like this.*

Issues relating to transport, location, the time of the appointment and the time spent waiting at the appointment were discussed as a matter of importance in most consultations, with particular focus on issues such as parking and the time taken both to get to the appointment and to be seen. The issue of cost associated with getting to the appointment was only mentioned on one further occasion and the issue of the facilities available was either not mentioned, or seemed to be relatively unimportant when the interviewer probed this issue.

Referral waiting times and expertise continued to be important themes running through all interviews. Content analysis of preferences for referral waiting time suggested that the maximum times that informants felt they should have to wait for an appointment were all less than 4 months. Current policy is that waiting times should not

exceed 3 months, and trial data at an interim analysis indicated that mean waiting times in the two arms of the trial were 8 weeks (hospital) and 4 weeks (PCDS).

Exploration of means of capturing expertise suggested two main possibilities. The first was to use some estimate of the likelihood of the skin condition being satisfactorily resolved; the second to specify expertise in terms of experience and training. The first option was discarded on the following grounds: that it would be difficult for respondents to understand; that there is no clear way of linking different likelihoods of resolution with any single practitioner type; and that it might be difficult to obtain realistic chances of resolution that are applicable across very heterogeneous conditions. Instead it was decided to use experience in treating skin conditions as the basis for the expertise attribute on the grounds that time spent training and treating conditions can be linked to knowledge gained and thus expertise. As far as possible, the minimum length of prior experience was specified for each of the two forms of care. Information about training times for specialists was obtained from local doctors. The typical time spent training for a consultant would be at least 5 years practising exclusively in dermatology; the typical time spent training for a GPSI would be 1–2 years part-time. It became apparent in discussions with dermatologists, however, that patients receiving outpatient care could be seen by a member of the consultant's team, rather than necessarily by the consultants themselves, and the wording of the expertise attribute was altered to reflect this possibility.

Conclusions from iteration 2 and issues to pursue in iteration 3

As informants frequently commented on the quality of their consultation, it was decided that individualised care was sufficiently important in the transcripts to become an attribute in the discrete-choice analysis. Difficulty remained, however, over how precisely to conceptualise this concept, given the variety of ways in which it had been expressed by informants. It was decided that the third iteration of the qualitative work would pursue the best terminology for expressing this concept.

At this stage, attributes related to the practicalities of accessing the service were combined into one, best described as convenience, for pragmatic reasons. First, different aspects of convenience were particularly important to different informants depending on factors such as whether they had access to a car (in which case parking was important, with public transport being important otherwise), whether they needed to take time out from work to attend an appointment, the journey time involved, and whether they wanted to combine the appointment with other activities such as town-centre shopping. Second, some issues to do with the locations of the clinics were highly dependent on the particular service and their inclusion would not have been helpful in generalising the work. Third, the aim was to keep the number of attributes as manageable as possible for respondents,

subject to including the crucial concepts of care. Wording for this attribute initially contrasted two levels: 'easy to get to' and 'difficult to get to', but the aim was to examine this wording in the next iteration.

Issues to do with the (non-medical) facilities available at different locations, and the cost of getting to appointments were concluded to be of relatively minor importance, and were not pursued from this point onwards.

The attribute for waiting was, as a result of this iteration, decided to be a four-level attribute including the maximum policy time (3 months), the times from the two arms of the trial (2 months and 1 month) and a time representing the ideal of most informants (immediate). Similarly, the attribute for expertise was decided to be a two-level attribute representing the experience associated with the consultant team and the GPSI with wording reflecting the issues discussed in the findings. These two attributes were now fully defined and no further work was needed for these attributes.

9.2.4 Iteration 3: confirmation

Methods

Methods at this stage focused on confirming the wording for the two concepts of individualised care and convenience. Different methods were used for each. For individualised care, a list was drawn up of all the different ways that previous informants had talked about individualised care. This was read out to new interviewees (with the list order varying between informants) and they were asked to choose which of the terms they felt best summed up what a good consultation would be. For the concept of convenience, the aim was to check that the terms the research team had developed conveyed the sorts of meanings intended. Informants were asked to explain what they thought 'difficult to get to' and 'easy to get to' would mean to them. These questions were asked during interviews conducted using the same basic topic guide as used in previous interviews. A further four informants were interviewed.

Findings

Informants talked about a number of different factors which related to a good consultation, including being listened to, the manner of the specialist and the specialist taking time to ask additional questions if they were felt to be important. When offered the list of terms, three out of four informants chose the wording thorough as the one which best summed up what a good consultation might be:

> *P16: It would probably be the last one – being thorough, you know, you don't go to the doctor for a good chat and a yarn! …The main point is to get reassurance or to get the problem sorted out…*

The remaining informant chose 'pays attention' as the term that summed up a good consultation and emphasised the importance of feeling that the specialist was interested in her.

Informants felt that 'difficult to get to' suggested inconvenient appointment times, long distances and parking problems, whereas an appointment that was 'easy to get to' suggested appointment times that fitted in with work responsibilities, public-transport accessibility, short distances and ease of practical access such as the use of ramps.

Conclusions from iteration 3

Given that three out of four informants had chosen one particular term for individualised care, it was decided to use the terminology of thoroughness in the final version of the discrete-choice experiment. With respect to issues of convenience, although not ideal because of the number of distinct sub-categories subsumed by the overall concept, it was felt that informants were thinking of the same basic issues as the researchers in relation to 'difficult to get to' and 'easy to get to'. A further element related to the time taken was added to the wording of this concept to further clarify the meaning.

The final attributes and levels are listed in Table 29.

Table 25 Final attributes and attribute levels chosen for the discrete-choice experiment

Concept	Level	Descriptor
Time waited	0	You will have to wait 3 months for your appointment
	1	You will have to wait 2 months for your appointment
	2	You will have to wait 1 month for your appointment
	3	Your appointment will be this week
Expertise	0	The specialist has been treating skin complaints part-time for 1–2 years
	1	The specialist is in a team led by an expert who has been treating skin complaints full-time for at least 5 years
Convenience	0	Getting to your appointment will be difficult and time-consuming
	1	Getting to your appointment will be quick and easy
Individualised care	0	The consultation will not be as thorough as you would like
	1	The consultation will be as thorough as you would like

9.3 Discrete-choice experiment

9.3.1 Methods

Experimental design

The design of the discrete-choice experiment is important. There are a number of experimental designs available, with health economists having tended to favour the use of pair-wise comparison. In these designs, each choice set consists of two options, each with different specifications of the service, and respondents are asked to choose between the two options. Scenarios are grouped into manageable choice sets through experimental design software that takes into account statistical properties of orthogonality and the need for a balanced design and minimal overlap. Regression techniques are used to analyse responses.

There are limitations with this experimental design. The design does not easily provide information about the relative importance of attributes and does not allow meaningful estimation of economic welfare unless a 'reject both' option is included. Alternative study designs, which do enable assessment of the relative importance of attributes, are required. The most appropriate here is the best–worst scaling approach. Of the alternative approaches available, this imposes least burden on respondents. Respondents are presented with choice sets of size one and asked to decide whether to choose or reject this option. They are then asked to identify the best and worst attribute within that option. The best–worst scaling approach was used here.

Given the set of attributes and levels derived during the qualitative work, the following website was used to obtain an array as the basis for reducing the number of scenarios presented to respondents to a manageable level:
http://www.research.att.com/~njas/oadir/oa.16.5.4.2.txt

This resulted in an array of five columns by 16 rows, providing the basis for an efficient design for five attributes each with four levels, where the worst attribute is denoted 0 and the best 3. This array was then reduced to fit the 4,2,2,2 set of dimensions obtained from the qualitative work by first omitting the second column to reduce the number of attributes to four as desired and then changing the last three columns to represent attributes with two levels rather than four by collapsing the levels; that is, by recoding 0 and 1 to equal 0, and 2 and 3 to equal 1. This resulted in an array of eight rows by four columns as indicated below.

0	0	0	0
0	1	1	1
1	0	1	1
1	1	0	0
2	1	0	1
2	0	1	0
3	1	1	0
3	0	0	1

Such a design would be efficient for estimating the main effects for each of the attributes, but would not allow estimation of any interactions. Unfortunately, when using a best–worst design, the estimation of sub-sets of two-way interactions is not possible: all two-way interactions must be estimated, or none. To do the former requires a so-called Resolution 5 design (a design in which all main effects and two-way interactions can be estimated orthogonally). While the simplest Resolution 5 design is often the orthogonal main effects plan (OMEP) plus its foldover (see below), in this instance such a design requires an additional assumption to hold, namely that attribute(s) with more than two levels must be continuous and linear in the levels. This enables it (them) to be collapsed to a two-parameter (constant plus slope) attribute. If this assumption does not hold, unfortunately the next smallest Resolution 5 design is often the full scenario design (in this case requiring 32 appointments to be considered by each respondent).

To enable main effects plus all two-way interactions to be estimated (on the assumption that the waiting-time attribute would prove to be linear), the foldover (from 0 to 1 and vice versa for two-level attributes, from 0 to 3 and vice versa and from 1 to 2 and vice versa for the four-level attribute) of the matrix resulted in a further eight sets of options:

3	1	1	1
3	0	0	0
2	1	0	0
2	0	1	1
1	0	1	0
1	1	0	1
0	0	0	1
0	1	1	0

To obtain a random ordering of the 16 scenarios, the ordering above was numbered from 1 to 16 and then randomly ordered using Stata. Further, the attributes A, B, C and D were initially ordered as they had

been derived from the qualitative work, suggesting that the order obtained was in some sense related to the ease with which these attributes had been identified, and thus, possibly, their relative importance. Again, to avoid this potential difficulty, the order in which the attributes should appear in each scenario was obtained randomly using Stata.

Randomised sub-study

There are a number of methodological issues associated with the use of the best–worst technique for estimating discrete-choice models. One of the most important concerns how easy or difficult the questions are to answer and thus the likely response rates.

The main version of the questionnaire had 16 appointment scenarios for respondents to consider, allowing for the estimation of the main effects for the discrete-choice model *and also* all two-way interactions (on the assumption that the waiting-time attribute would prove to be linear). It was anticipated, however, that when received as a postal questionnaire, this might be a large number of scenarios for respondents to cope with. The smallest number of scenarios with which respondents would be faced was eight, allowing estimation of the main effects only. It was not clear which of these two options was best in terms of the potential impact of a larger number of scenarios upon response rates. It was therefore decided to conduct a randomised sub-study, in which respondents were randomised to receive one of two versions of the questionnaire:

Version 1: 16 scenarios; or

Version 2: a smaller version of the questionnaire with the eight main effects scenarios and excluding the foldover.

The primary aim of the randomised sub-study was to identify any differences in response and completion rates across the two versions of the questionnaire, in essence to determine the trade-off between a more comprehensive model and a potentially less representative sample. A secondary aim was to investigate any bias in the estimates from the short questionnaire should the longer one provide evidence of interactions.

Sampling

All patients were sampled from those who had been referred for an appointment but had not yet received it. This mirrors the 'choices' that people have with regard to attending (or not) a secondary-care appointment, and ensures that preferences are not influenced by the service that has already been received. By capturing the whole group of patients at this point, patients who – for one reason or another – would not in practice attend their appointment should be sampled as well as those who do, in practice, choose to attend.

Sample sizes were based on the desire to obtain a minimum of between 30 and 100 individuals per sub-group of interest (Pearmain *et*

al., 1991). The qualitative work identified two potential sub-groups of interest: those with chronic long-standing conditions, and those with acute conditions mainly requiring diagnosis. The aim was thus to achieve, on average, a sample of 30 individuals per sub-group (i.e. 60 in total). The randomised element of the study necessitated a doubling of the sample size with the aim of achieving 120 responses across the two arms of the trial. Questionnaires continued to be sent out until at least 60 complete responses were achieved in both arms of the trial. Information was kept about all questionnaires sent and returned so that response rates and completion rates in both arms of the trial could be calculated.

Data collection

Data were collected by postal questionnaire sent to the respondent's house. Individuals who had been referred to secondary care and triaged as being appropriate for care within the PCDS were sent a letter from the secondary-care service asking for their consent to participate in the research. The letter sent included an information sheet and consent form, and was returned to the Department of Community Medicine. Upon receipt of signed consent forms, a study number was allocated to each respondent and a pre-numbered envelope containing one of the two versions of the questionnaire was sent. This questionnaire was randomly selected and placed in the envelope by a member of the research team not involved in the subsequent allocation of study numbers and posting of the questionnaires. For initial non-responders, up to two reminders to complete the questionnaire were posted.

Data analysis

Information from completed questionnaires was input into an access database, based on the questionnaire. Data from the randomised controlled trial comparing the long and short versions of the questionnaire were analysed in terms of response rates and completion rates.

Regression techniques using weighted least squares and multinomial logit regression, and based on the random utility model, were the basis for analysing the best–worst data from the discrete-choice experiment. This allows the estimation of the relative importance of the different attributes to individual preferences for access to dermatology services, and the rate at which people will give up one attribute to gain more of another. Best–worst data can be analysed in either an aggregated or disaggregated format. Here, for the aggregated format, the data were analysed using the 'full' rather than the 'restricted' method (Marley and Louviere, 2004). In this method each possible best–worst pair is treated as a unique datapoint. In presenting the data, the worst attribute level has been rescaled to zero; values for each attribute can be interpreted as the additional utility provided by a particular attribute and level, compared to the

attribute level providing the lowest level of utility. (In interpreting these data, it should be remembered that these values are on an interval rather than a ratio scale.) Adjusted R^2 values are given for each model as an indication of how much variation is explained by the model.

Separate analyses were also conducted to compare whether groups who, from the qualitative work, might potentially have different preferences did indeed show such differences. Those patients who had seen their doctor only once or twice before referral and who had initially made contact with their GP with regard to their skin problem less than 6 months ago were analysed as one group, those most likely to be seeking diagnosis from secondary-care services. Patients who had first made contact with their GP regarding their skin problem over 1 year previously were considered as a separate group, more likely to have a chronic skin problem.

Data were also analysed on the basis of the accept/reject question, using traditional stated-preference discrete-choice modelling methods, using the random-effects logit model to adjust for clustering in individuals' responses.

Data from the long and short versions of the questionnaire were analysed separately. Stata was used for analysis. Throughout the data analysis presented here, missing observations were omitted with no attempt to impute data. (At present there is little guidance on imputing choice data in a random utility model.) In presenting the results, all values are reported to three significant figures.

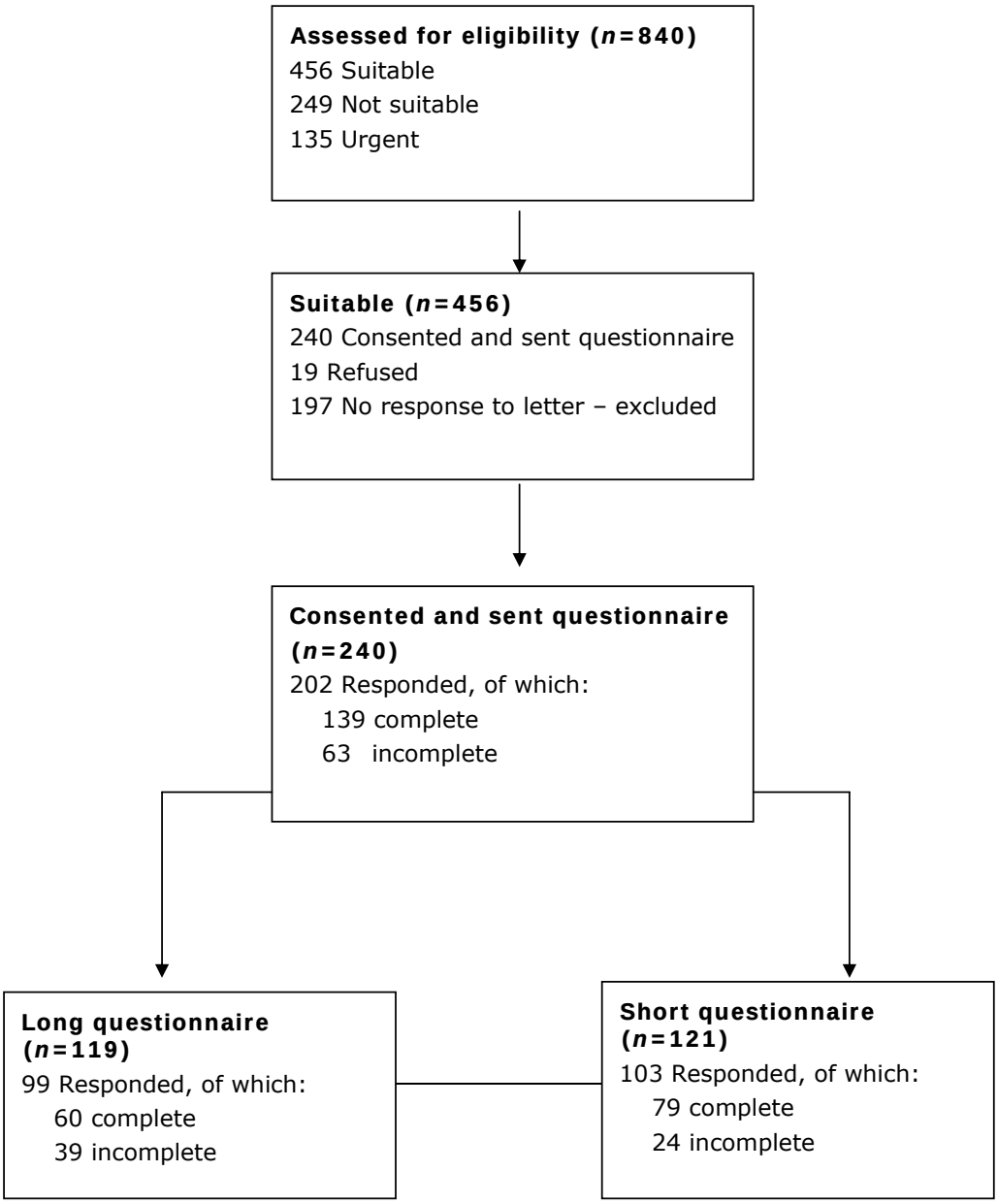
9.3.2 Results

Randomised controlled trial

Eight hundred and forty patients referred to secondary-care dermatology services (who were not participants in the main trial) were assessed, on the same basis as for the main trial, for their suitability to receive the new PCDS service. Of these, 456 were found to be suitable and were invited to take part in the discrete-choice experiment; 240 of these agreed to take part (see Figure 8).

Two hundred and forty questionnaires were sent, with respondents randomly allocated to receive the long and short versions of the questionnaire. The response rate to the long questionnaire was 83.2% (99/119) and to the short questionnaire was 85.1% (103/121). The difference in response rates was therefore 2% (95% CI, –7–11%). The vast majority of returned questionnaires contained sufficient best–worst data for analysis (97/99 of the long questionnaires; 102/103 of the short questionnaires).

Figure 8 Recruitment flow diagram for the discrete-choice experiment



Findings from the discrete-choice experiment

Results from the long and short versions of the discrete-choice experiment are given in Tables 30 and 31. The model derived from the long questionnaire has a high adjusted R^2 of 0.86, suggesting that around 86% of the variation in responses was suggested by the models; the corresponding value for the shorter questionnaire is lower, at 0.71. In both cases, the attribute providing the lowest level of utility to respondents was that of 'The consultation will not be as thorough as you would like.' Tables 30 and 31 show the additional utility that would be gained for each level of each attribute, compared with the attribute level indicating lack of thoroughness in the consultation. Both tables show very similar findings, with lower levels of utility for each of the lower level attributes and higher levels for all of the highest levels of the attributes. The greatest difference in utility arises for the thoroughness of the consultation, a difference between zero and 3.33 for the long questionnaire and zero and 2.52 for the short questionnaire. Shorter waiting times, higher degrees of expertise and greater convenience also produce higher levels of utility, although greater convenience seems to be the least important of these in both versions of the questionnaire. The model derived from the long version of the questionnaire is also shown graphically in Figure 9.

Table 26 Utility values obtained from the long version of the questionnaire

Attribute	Utility	95% CI	*P* value
Waiting time			
3 months	0.548	(0.284–0.813)	<0.001
2 months	0.828	(0.541–1.12)	<0.001
1 month	1.38	(1.06–1.70)	<0.001
This week	2.52	(2.21–2.82)	<0.001
Expertise			
Part-time specialist	1.48	(1.18–1.79)	<0.001
Team led by expert	2.84	(2.52–3.16)	<0.001
Convenience			
Difficult	1.26	(0.943–1.58)	<0.001
Easy	2.10	(1.76–2.44)	<0.001
Consultation			
Thorough	3.33	(2.95–3.70)	<0.001

Table 27 Utility values obtained from the short version of the questionnaire

Attribute	Utility	95% CI	*P* value
Waiting time			
3 months	0.111	(−0.240–0.462)	0.529
2 months	0.265	(−0.155–0.684)	0.212
1 month	0.905	(0.484–1.33)	<0.001
This week	2.44	(1.93–2.94)	<0.001
Expertise			
Part-time specialist	1.29	(0.91–1.68)	<0.001
Team led by expert	2.46	(2.01–2.91)	<0.001
Convenience			
Difficult	0.714	(0.304–1.13)	0.001
Easy	1.71	(1.22–2.21)	<0.001
Consultation			
Thorough	2.52	(2.00–3.04)	<0.001

Figure 9 Attribute level utilities from the analysis of the best–worst data contained in the long questionnaire

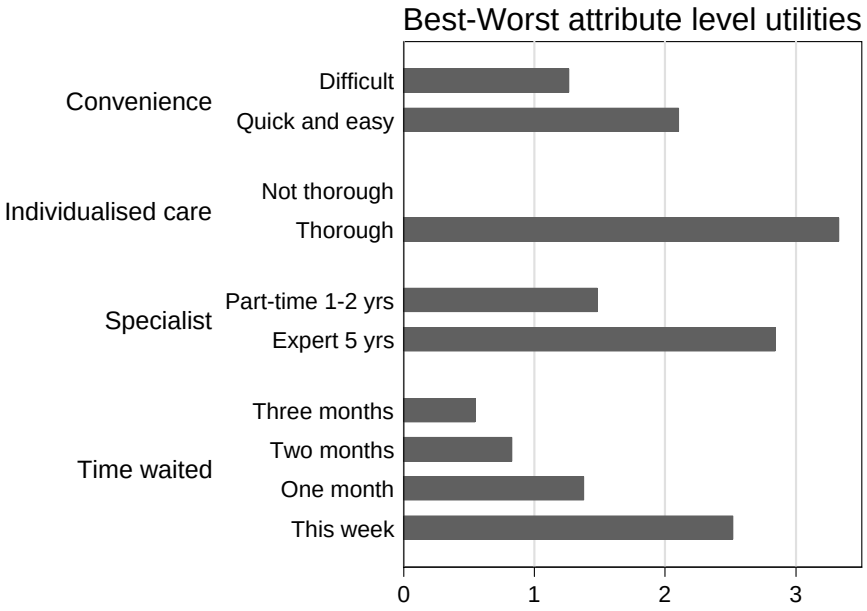


Table 32 shows the importance weights for the attributes for the long questionnaire. These are calculated by taking the average across all levels of utility for each attribute and indicate how important an attribute is generally to respondents, when abstracting from particular levels.

Table 28 Attribute importance weights obtained from the long version of the questionnaire

Attribute	Weight
Waiting time	1.32
Expertise	2.16
Convenience	1.68
Consultation	1.67

The equivalent results for the short questionnaire are shown in Table 33. These display the same pattern of importance weights as those for the long questionnaire.

Table 29 Attribute importance weights obtained from the short version of the questionnaire

Attribute	Weight
Waiting time	0.93
Expertise	1.88
Convenience	1.21
Consultation	1.26

Separate analyses for the two different groups of patients (those with long-term chronic skin problems, and those whose skin condition was of a more short-term nature) showed the same pattern of the data as for the overall analysis, and no further analysis of these separate groups was undertaken.

Further analysis of the data considered the extent to which different potential policy changes or improvements in service would improve utility. Table 34 shows the results from the long questionnaire of a further analysis based on respondents' decisions about whether they would accept or reject a consultation. Here the worst type of consultation provides the constant level of utility: an appointment with a 3-month wait, seeing the part-time specialist, difficult in terms of convenience and not thorough would have a negative utility of –0.463. Considering the data in Table 34 it seems that only a change from a consultation that is not considered to be thorough to one that is considered to be thorough, or a change in the expertise of the doctor, are sufficient to improve the utility associated with the consultation to be higher than zero and hence, on average, attend rather than not attend the consultation. Changes in convenience appear to be particularly unimportant.

Table 30 Additional utility that can be gained from movement from the lowest level of all attributes (analysis based on acceptance or rejection of each scenario in the questionnaire)

Attribute	Utility	95% CI	*P* value
Constant	−0.463		
Waiting time			
2 months	0.297	(0.0227–0.571)	0.034
1 month	0.426	(0.149–0.703)	0.003
This week	0.435	(0.069–0.800)	0.020
Expertise			
Team led by expert	0.943	(0.654–1.23)	<0.001
Convenience			
Easy	0.185	(−0.005–0.375)	0.056
Consultation			
Thorough	1.63	(1.30–1.96)	<0.001

The degree to which respondents are willing to trade one attribute for another can be quantified by calculating the marginal rates of substitution between attributes for the best–worst data: the number of additional months that respondents were willing to wait in order to obtain the 'upper' level of a given attribute, rather than the 'lower' one, is calculated by dividing the difference in utility between levels of that attribute by the mean utility of a month's waiting time. The latter was calculated by re-estimating the best–worst regression using a linear term for waiting time (results not shown). For the long questionnaire respondents were willing to wait an additional 2.1 months to see a team led by an expert or an additional 1.3 months to attend a consultation that is easy to get to. Although it is possible to calculate a marginal rates of substitution for individualised care, the figure of 5.3 months for the additional wait to receive thorough rather than not thorough care should be treated with caution: extrapolating beyond the levels presented in the questionnaire is unwise. For the short questionnaire the marginal rates of substitution were 1.8, 1.5 and 3.8 respectively.

Section 10 Discussion

10.1 Summary of findings

10.1.1 Randomised controlled trial

There was no evidence that patients seen at the PCDS obtained different clinical outcomes compared with those seen at the hospital outpatients' clinic. The PCDS was viewed as more accessible, and patients expressed slightly greater satisfaction with their consultations in this setting. In particular they were more satisfied with the length of time they were given. Patients were also slightly more satisfied with the facilities at the PCDS.

The waiting time for an appointment at the PCDS was considerably shorter than for an appointment at the hospital (72 compared with 113 days). In the absence of the recruitment and randomisation procedures necessary for the trial, the waiting times at the PCDS would have been shorter and the difference compared with the hospital greater still.

About half (49%) of all those patients referred to the hospital initially were triaged as being suitable for management in the PCDS, and only 12% of patients seen at the PCDS subsequently had to be referred on to the hospital. However, the overall follow-up rate for patients seen at the PCDS was slightly higher than for hospital patients.

At the time of their referral, most patients (61%) expressed a preference to be seen at the PCDS, but after their appointment most patients preferred to be seen in future at whichever site they had been randomised to.

10.1.2 Economic analysis

The costs to the NHS of the PCDS were considerably greater than the costs of hospital outpatient care. This was mainly due to the higher costs of doctors' and nurses' time, which was related to the longer consultations at the PCDS, the higher number of consultations received by patients in the PCDS and the higher cost of nurse consultations. The cost to patients of attending the PCDS was less than that of attending the hospital, as was the cost of lost production. This was due to the finding that patients attending the PCDS lost less time from work. Overall, when NHS, patient and lost production costs were combined, the cost of providing care at the PCDS was greater than the cost of providing hospital outpatient care.

For GPSI services there is a very slightly increased benefit in terms of outcome, but this is minimal. There are, however, benefits in terms of access, satisfaction, waiting and facilities in the GPSI service. The

cost-effectiveness acceptability curve for the access scale suggests that a decision-maker who is willing to pay £100 for an improvement of 10 points in the access scale would always find the GPSI scheme cost-effective.

10.1.3 Analysis of waiting times and demand

The analysis of routine data suggested that waiting times had been stable at the study hospital before, during and after the establishment of the PCDS, suggesting that the expansion in capacity represented by the PCDS did not lead to a reduction in waiting times. By contrast, waiting times at three neighbouring trusts reduced over the same period, so that by the end of the data-collection period (June 2004) waiting times had converged to about 70 days in all four trusts. It is noteworthy that the average waiting time for outpatient appointments for patients in the randomised controlled trial was longer – at 113 days – than the average experienced by all patients. This may be because the trial excluded patients with urgent problems.

The analysis of referral rates showed that the number of referrals from GPs to dermatology services was rising in three of the four trusts studied and was stable in the other trust. However, the rise was greatest in the trust with the PCDS, raising the possibility that this new facility had led to induced demand.

10.1.4 Qualitative research

It appeared from the qualitative study that the variables of most importance to patients seeking specialist help with a skin problem were the location of the service, the perceived expertise of the professional to be consulted, the wait for an appointment and the quality of the consultation itself. Participants in the interviews mainly welcomed a primary-care-based dermatology service if it led to shorter waiting times with equally effective care, although this was clearly related to their perception of the severity of their skin complaint. However, the observed variation in participants' views of the constituents of specialist expertise suggests that for some patients a service staffed by GPSIs rather than consultants would be a less acceptable substitute. These were likely to be patients with painful or long-standing conditions treated unsuccessfully by their own GP. Participants with a hierarchical understanding of medical expertise, who identified the consultant as the apex, were also likely to be less happy with a referral to a PCDS. These findings, though not necessarily generalisable, may have implications for health-services planners.

In this study GPs assisted patients to make healthcare choices. A number of participants chose to attend the PCDS because their GP advised of a lengthy wait to be seen at the hospital. GPs can influence their patients by their use of language to describe services; avoidance of terminology such as 'top man', which suggests value judgements in

the relative expertise of practitioners in dealing with comparatively minor skin conditions, could encourage some suitable patients to use the service provided by the GPSI.

Some participants expressed dissatisfaction with their own GP's apparent lack of understanding of the problems they encountered with their skin condition. In contrast, participants who equated high-quality care with consultant care were more forgiving of a cursory examination or interview. Participants who described these experiences appeared to consider a less thorough examination or short interview as an acceptable trade off for the knowledge and skill a consultant could bring to bear on their problem as a result of their greater expertise.

The location chosen for a primary-care-based service was of great importance. For most potential users it was unlikely to be local to their home or work. Although most of those interviewed valued the ease of free parking at the PCDS and were not unduly dismayed by the journey, many commented on the limited appropriateness of a location deep in an outlying estate and felt it should be positioned on a main road. For participants without ready access to a car the location was a barrier due to the poor public-transport links necessitating a long and slow journey, and attending a city-centre hospital was more convenient.

10.1.5 Discrete-choice modelling

All attributes identified by the qualitative work as potentially important to those receiving dermatology services were found to be quantitatively important. When abstracting from individual levels (which can potentially be altered to give different inferences concerning service improvements), the best–worst analysis does indicate that when designing a system of dermatology consultations, the attribute of most absolute importance to patients is that of expertise of the doctor whereas that of least absolute importance is waiting time. However, the utilities associated with the individual levels are useful in evaluating marginal changes in service provision. Improvements in access-related issues such as waiting times or convenience were, on the whole, less important than those related to the consultation – the expertise of the doctor and the thoroughness of the consultation. Furthermore, the marginal rates of substitution for these attributes indicate that whereas patients are willing to accept a 2-month wait in order to see a consultant-led team rather than a part-time doctor, there is no amount of time (allowable within current service provision guidelines) that they are willing to wait to receive a thorough consultation.

10.2 Methodological strengths and limitations

The strength of this study relates to the fact that it is based on rigorously collected data from patients with similar characteristics randomly allocated to a GPSI service or usual outpatient care. To our knowledge this is the first randomised trial of a GPSI service, as previous reports have been based on observational studies and routinely collected data. Such studies are prone to selection bias because different types of patients will be referred to different services, and the limitations of routinely collected data within the NHS are well recognised.

The main limitation of the randomised controlled trial relates to the fact that it was conducted in just one PCT area and in relation to one clinical condition. The GPSI service studied is relatively small, comprising just two GPSIs and one nurse. This is typical of many such services but there are examples of larger GPSI clinics in some areas.[c] It is not known whether the findings from this research would apply to another geographical areas, to other models of organisation or to other clinical specialities. However, dermatology is one of the most common clinical specialities chosen for GPSI services in other PCT areas (Jones and Bartholomew, 2002), and there is good reason to suggest that the findings from this study about the accessibility and acceptability of GPSI services, and the trade-offs that patients make between issues such as access and expertise, are likely to be relevant to other clinical areas.

The strengths and limitations of a trial such as this randomised at the level of the individual, rather than at the level of the practice, were discussed in Section 3.3.

In terms of the generalisability of this research it is important to note that the model of referral which was used in the PCDS, where all referrals are made via the hospital dermatology service and then triaged for suitability for primary-care treatment, is relatively unusual. Most GPSI services appear to allow direct referral from GPs to the GPSI.

Only 65% of eligible patients agreed to participate in the study. This could reduce the generalisability of the findings, if those participating have different characteristics from those declining to participate. It appears that many of those declining to participate did so because of a preference for the hospital (because of location or wanting a consultant service) rather than because of a reluctance to be involved in research, so to some extent those in the trial were a selected population who were amenable to the possibility of being randomised

[c] I. Mauri-Sole, personal communication, based on a survey conducted by the Primary Care Dermatology Society.

to the PCDS. This may have implications for the acceptability of the service to patients if in future all suitable patients are transferred there.

The follow-up rate of 76% is slightly lower than anticipated, and there is a slight difference between the two arms of the trial in the response rates both after the initial consultation (questionnaire 2: PCDS arm, 81%; hospital arm, 74%) and after 9 months (PCDS arm, 73%; hospital arm, 78%).

It is possible that some people were lost to follow-up because they had got better and were less interested in the study, in which case the findings would under-estimate the improvement over time, or conversely that they had got worse in which case the improvement would be over-estimated. However, it is important to note that the attrition in follow-up only relates to those measures dependent on patient questionnaires, as the data obtained from patients' records were virtually complete.

The slight difference in the follow-up rates between the two arms of the trial is potentially more serious. This raises a possibility of non-response bias if patients who failed to respond had different costs, outcomes or perceptions from those who did respond, although the sensitivity analysis of the impact of imputing missing data suggested that this was unlikely to be a problem.

The economic evaluation also had limitations. Because of some missing questionnaire data, the patient costs and costs of lost production are estimated on a sub-sample of respondents. There is debate about how best to account for missing data in this type of study. Further analysis of the findings after imputing missing data was undertaken and has no marked effect on the overall conclusions. Secondly, there were difficulties in valuing consultation costs at the hospital in terms of obtaining information about overheads and for this reason estimates for overheads based on national figures were used. Thirdly, there are differences in the way in which information about investigations, procedures and medication are recorded at the PCDS and the hospital which may have influenced the accuracy of the data captured for the economic evaluation. However, these items together represented a relatively small proportion of the NHS cost of a consultation and differences in recording are unlikely to affect the overall finding that hospital care is cheaper than the PCDS.

The assessment of the costs of the PCDS may offer some general messages of relevance to other GPSI services, but it may also be more context-specific. The costs of GPSI services are likely to be affected by the volume of activity, the number, range and salaries of specialist doctors and nurses, and the proportion of those referred to a GPSI service who are subsequently transferred to a hospital outpatient clinic. Although it is likely that the results obtained in this study are representative in terms of GPSI dermatology services, costs for other types of GPSI service may be very different.

Clearly the salaries paid to the GPSIs in this study are an important factor in the costs of the service, and these vary considerably in different areas and specialities. However a survey conducted by Dr Sue Jackson as part of the Action on Dermatology programme showed that the GPSIs in Bristol are paid at the lower end of the range nationally, and in some other areas GPSIs are being paid the costs of employing a locum as well as their salary.[d] This would suggest that some other GPSI schemes are even more expensive.

During much of the period during which this study was conducted the PCDS was not operating at full capacity. This was due to a number of factors. First it was anticipated that the staff would need spare time to set up the service, develop protocols and gain experience before they committed all of their time to direct patient care. The proportion of appointments being booked increased over time. Second, the existence of the randomised trial meant that more appointments were planned for than ultimately needed. Third, although efforts were made to fill this 'trial-induced' spare capacity, the appointments office at the hospital did not make full use of the appointments available. Finally the system used at the PCDS whereby patients could phone and choose an available appointment time that suited them meant that some appointment slots were unfilled. The consequence of this spare capacity was that the PCDS would appear more expensive than if it operated at full capacity. This issue was explored in a sensitivity analysis in Section 6, which showed that reducing the number of unfilled appointments would make care in the PCDS less costly but would not change the overall conclusion that care in the PCDS in more expensive than hospital outpatient care.

The data presented in Section 7 about waiting times and demand should be interpreted with some caution, as they are routinely collected data originating from several trusts, which have not been externally validated. Complete data were only available for patients registered with GPs in Avon PCTs being referred to and seen at one of the four providers of dermatology outpatients in Avon; no account is taken of referrals and activity beyond this. The analysis cannot take account of variations in capacity due to factors such as staff/public holidays or sickness, loss of dermatology outpatient sessions in early 2002 to support the pilot study or complications such as patient cancellations. Other factors such as waiting-time targets will have an impact: the convergence of mean waiting times across the four PCTs may reflect the waiting-time targets in the NHS Plan, including the target to reduce the maximum wait for outpatient appointments to 3 months by the end of 2005.

The qualitative study was limited by the fact that only a minority of those patients approached agreed to be interviewed. Although the

[d] S. Jackson, Broadgreen Hospital, Liverpool, personal communication.

study described the experiences of self-selected volunteers, purposeful sampling within the group who agreed to be interviewed ensured an even spread of age, sex, presenting symptoms, proximity to the service and those who had experienced care compared to those who had not.

The best design for discrete-choice experiments is debated, and the limitations of the pair-wise comparison designs usually used are increasingly recognised (Flynn *et al.*, 2005). This study was based on a relatively new form of experimental design and provided the opportunity to undertake some methodological development by randomising participants to two different versions of the questionnaire.

One general limitation with regard to this evaluation is that it only involves adult patients who were referred to the outpatient dermatology service. This was because of the need to maintain strict comparability between the two arms within the randomised controlled trial. However, the aims of the PCDS (and most other GPSI services) were not purely to substitute for normal outpatient care, but were also to provide new forms of care. In particular the specialist nurse provided educational sessions, mainly for children, and support and informal advice to practice nurses. The impact of this work was not studied in this evaluation because it would be very difficult to identify the relevant population for a comparative study, given that many of the patients receiving advice directly or indirectly from the specialist nurse would not otherwise have been referred to hospital. In addition, children were excluded for the reasons discussed in Section 4.1.

10.3 Relationship with previous findings from research

The findings from this study are largely consistent with those from other research and descriptive reports. The Audit Commission conducted an in-depth assessment of new care pathways, mainly based on GPSI services, in 10 PCTs and found that the new services had short waiting times of between 1 and 4 weeks (Audit Commission, 2004). However, in only two PCTs did there appear to be evidence that this was associated with any reductions in waiting times at the relevant hospital outpatient department. The Audit Commission study also found that at least half of the patients referred in a range of service-redesign projects could be treated in the community without the need for attending hospital outpatients, and this is also consistent with the findings from this research.

A recent study conducted by Rosen and colleagues included an observational study of GPSI services in four PCTs, three of them in the field of dermatology (Rosen *et al*., 2005). Quantitative data were collected about costs, outcomes, waiting times, referral rates, patient experience and GP satisfaction with the services. Qualitative interviews were held with professional stakeholders. The authors found no consistent evidence that GPSI services were associated with

better or worse outcomes or patient satisfaction than the hospital services used as controls, although patients did find GPSI services easier to get to. Conclusions about costs were difficult to draw because of a lack of consistency in the financial data available. As with the Audit Commission (2004) study, although waiting times at GPSI services were shorter than at hospital, the extra capacity did not appear to lead to reduced waiting times for appointments at hospital clinics, possibly because the extra capacity provided was relatively small.

The study by Rosen *et al*. (2005) usefully complements the research reported here, in that the observational nature of Rosen's work has more design limitations and is based on data of less certain reliability, but the wider nature of her research provides greater generalisability. It also provides much useful information about the perspective of stakeholders. It is notable that the two approaches led to very similar conclusions.

The overall conclusions from our study are also consistent with earlier research about consultant outreach clinics in primary care, many of which were established in relation to the GP fundholding initiative. Studies of these clinics in a variety of geographical areas and clinical specialities consistently showed that they were associated with high levels of patient satisfaction but at greater cost, and inconsistent effects on referral rates and waiting times (Gillam *et al*., 1995; Black *et al*., 1997; Bowling *et al*., 1997; Bowling and Bond, 2001; Powell, 2002; Maddison *et al*., 2004).

The largest such study was conducted by Bowling and Bond (2001) and evaluated 38 outreach clinics in comparison with 38 matched hospital outpatient clinics. Measures of processes, costs, patient experience and health status were included with follow-up for 6 months. Surveys of GPs and specialists explored professional perspectives about these clinics. Patients found outreach clinics to be more accessible and convenient, and they also had slightly better health outcomes. The cost to patients of these clinics was less than they incurred in attending outpatients, but the NHS costs of outreach clinics were considerably higher.

Bowling and Bond's study was very ambitious and has the merit of generalisability because of its size and scope, covering a range of geographical areas and clinical topics. However, it shares the problem of the recent study by Rosen *et al.* (2005), inherent in observational designs and particularly relevant to the issue of community-based clinics, of differences between patients seen in the community and the hospital. For example, in Bowling's evaluation 65% of the patients sampled in community clinics were new patients compared with 31% of the outpatient sample (Bowling and Bond, 2001).

A systematic review of 15 studies of specialist outreach clinics, of which eight were comparative studies and seven were surveys, was conducted in 2001 (Powell, 2002). The perceived advantages of

specialist clinics were improved patient experience and access, and improved communication between GPs and consultants. Patients expressed a preference for community-based clinics, and measures of patient satisfaction and convenience were generally higher for these clinics. No consistent differences were found in health outcomes but outreach clinics were generally more costly than hospital outpatient clinics.

All of the above studies are related to outreach clinics delivered by hospital-based specialists, rather than GPSIs, but the findings are consistent with those obtained in this research. It is important to note that in many other countries throughout Europe and North America specialists provide a range of services in community clinics, without patients needing to attend hospital (Rosen *et al*., 2003). In many cases patients have direct access to these specialist clinics, without referral from a GP. In the current study in the UK context it is difficult to know whether the advantages and disadvantages identified with regard to the PCDS relate to the community location, or to the clinical background of a GPSI compared with a consultant, or some combination of these factors. Given that the main benefit was greater accessibility and the main disadvantage was greater cost it is likely that these relate to the community location of the clinic, rather than the type of health professional providing care.

10.4 Implications for policy

There have been GPs with specialist interests working within the NHS in a variety of guises for many years (Jones and Bartholomew, 2002). However, following the NHS Plan (Department of Health, 2000) there was renewed interest in formalising and expanding the role of the GPSI. There are a number of reasons for promoting this concept, which can be implied from several policy documents (Department of Health, 2000, 2005; Royal College of General Practitioners, Department of Health, 2003) and have been suggested in earlier discussion documents (Williams *et al.*, 2002; Kernick, 2003; Nocon and Leese, 2004). The reasons for promoting the concept of GPSIs include the following:

- improved quality of service for patients,
- increased convenience,
- promoting patient choice,
- increased service capacity to address unmet needs,
- moving work from secondary to primary care,
- faster access with reduced waiting times,
- reduced costs,
- promoting skill mix,
- improved flexibility in GP careers, boosting recruitment and retention.

The reasons for establishing a GPSI service in a particular area may involve a combination of one or more of these considerations.

The above arguments for GPSIs will be discussed in turn, in light of the evidence from this research where this is applicable.

10.4.1 Improved quality of service for patients

The quality of service can be considered in terms of patient experience of care and also in terms of clinical outcome. The evidence from this study suggests that the patient experience of the PCDS was at least as positive as that provided to patients attending the hospital and there was no evidence that clinical outcomes were different. It is important to note that although this study achieved its recruitment targets and could detect differences between the two services within the parameters stated in the sample-size calculations, it is not possible to exclude the existence of small differences between the PCDS and the hospital in terms of clinical outcomes at follow-up. Most patients in this study had minimal impairment in quality of life even at baseline, as assessed using the DLQI, making it difficult to detect differences at follow-up between the two arms in the trial.

It is notable that the discrete-choice experiment suggests that the quality of individualised care is the top priority for most patients, and more important than issues of access or convenience. This suggests that it in designing a patient-led NHS it may be most important to seek to ensure that patients can have access to expert care. This should not necessarily be equated with hospital-based care, as a GPSI may have more experience than some of the more junior staff that undertake many consultations in outpatient clinics.

10.4.2 Increased convenience

One aim of GPSI services is to make them more accessible by providing local services which are more convenient for patients. There was good evidence from this study that the PCDS provided a more convenient service. This was partly related to the access to parking. In health and urban planning terms this is the opposite of Government policy, where it is hoped that people will use public transport, walk and cycle to access local facilities. The interviews conducted in the qualitative study also demonstrated that the question of accessibility and convenience is complex. Wherever a new primary-care-based service is based in an urban setting such as Bristol it is likely to be very convenient to those patients who live nearby but less convenient for some other patients who live closer to the hospital. In addition, it is important to consider public-transport links, which may be better to a city-centre hospital than they are to a suburban primary-care location. Both of these considerations will vary in different settings. In a rural PCT that is some distance from the nearest hospital a primary-care-based service may be more convenient for almost all patients. These factors highlight the importance of considering context in

planning GPSI services, rather than assuming that a model which is beneficial in one area necessarily has the same advantages elsewhere.

10.4.3 Patient choice

As previously discussed, patients in the randomised trial preferred the primary-care-based service. However, only 65% of those invited to participate agreed to take part in the research. Many of those who declined stated that this was because of an unwillingness to risk being referred to the primary-care-based service, rather than reluctance to take part in research. These comments often referred to unwillingness to travel to the primary-care service because of its location in a deprived council estate rather than because of concern about seeing a GPSI. Satisfaction with the service may have been lower if all suitable patients were automatically referred to the GPSI.

One justification for GPSI services has been to provide patients with a choice about where and when they are treated. If the referral system is designed to achieve this, as it will be under the 'choose and book' mechanism, then patients will be able to decide about the relative merits to them of seeing a particular type of practitioner or being seen in a particular location. The findings of the randomised trial component of this research could be interpreted to suggest that people will prefer to see the GPSI, but the low recruitment rate and the findings of the discrete-choice experiment may suggest they will prefer to see a consultant. At present it is not clear that all patients referred to GPSI services are given this choice.

10.4.4 Increased capacity

Dermatology problems account for one of the largest proportions of all outpatient referrals to hospital, and make up a high proportion of patients waiting more than 13 weeks for an appointment. In some parts of the country there are shortages of consultants, creating a bottleneck in the availability of care (Department of Health, 2003a). Many of the problems referred to dermatologists do not require hospital facilities. They may need attention from someone with a greater level of expertise than a GP, but not someone with the extensive training of a consultant. One way to increase the capacity of the service is to recruit GPs or nurses with a specialist interest.

The importance of capacity comes from the need to balance supply and demand to reduce waiting times and address unmet needs. Employing a GPSI is only one way in which capacity might be increased. Alternatives might include the employment of specialist nurses rather than doctors, employing non-consultant career-grade doctors working as associate specialists or at staff-grade level without them necessarily having primary-care experience, employing more consultant dermatologists where this is possible, or seeking to increase the proportion of time that existing consultants spend on patient care by delegating other tasks. Which is the best solution

depends on the specific skills that are necessary to meet the identified needs of patients and the costs and availability of the alternatives.

Kernick (2003) points out the importance of specifying whether GPSI services are intended to substitute for or add to secondary-care services. The PCDS service, along with most other GPSI services, is intended to achieve both of these aims to some extent. The most important issue is to allocate the resources in the most efficient way possible. Further research is required to compare the costs and benefits of increasing service capacity by employing a GPSI model or by the employment of more doctors of different types in hospital settings.

Providing additional capacity may reduce pressure on secondary-care services but it may also increase demand. This demand may represent unmet need, where extra service capacity is justified by demonstrable benefits to patients, or it may represent a lowering of the threshold for referral, without necessarily providing benefits to patients.

The design of this study does not provide strong evidence about the question of whether the PCDS leads to greater demand, although there was some suggestion in the data reported in Section 7.3.2 that referral rates had increased more in the study PCT than in neighbouring trusts.

With regard to the question of whether the extra capacity addresses unmet needs or lowers the threshold for specialist care to include people who would not benefit from it, the data presented about clinical outcomes is interesting. It could be interpreted to suggest that patients in both arms improved irrespective of the intervention, having only minor problems, as assessed by the DLQI at baseline, and hardly any problems at follow-up. Alternatively these findings could suggest that the DLQI is not a sufficiently sensitive measure for patients with minor skin problems.

Finally, the issue of increasing capacity raises questions about where this capacity is to come from. GPSIs may be a solution to the shortage of consultants in some specialities. However, GPs are themselves also in short supply in some areas, and increasing the capacity of the specialist service at the expense of the generalist primary-care service may not be necessarily be appropriate. The number of appointments lost in general practice for each session worked by a GP as a GPSI may be much greater than the gain in specialist appointments because of the longer appointment times in the GPSI clinic and the disproportionate training and administrative time required by a part-time specialist commitment.

10.4.5 Moving work from hospitals to primary care

One clear theme in current policy is to move work from secondary to primary care (Department of Health, 2002b). The importance of this is related to several other themes such as reducing waiting times for

specialist care for people needing hospital facilities, making services more local and accessible and reducing costs.

One clear message from this study is the success of the GPSI model in managing a high proportion of all cases currently referred to secondary care. The finding that GPSIs were able to deal with 49% of all referrals to the dermatology service, while only having to refer 12% of these patients back to the hospital, and that patients achieved equivalent clinical outcomes, suggests that they have appropriate skills for these patients.

The GPSI service was also more accessible for patients. But the evidence about the other drivers of the policy to move work from secondary to primary care is more mixed, in particular the impact on costs and on waiting times.

10.4.6 Faster access – reduce waiting times

The patients randomised to the PCDS experienced much shorter waiting times than those randomised to hospital outpatient care. Waiting times are dependent on the relationship between the demand and the number of available appointments, and can also be related to the organisation of the system for making appointments.

The waiting time for the PCDS was short because the PCDS was planned to provide at least as many appointments as were needed to meet the predicted number of patients referred. During the period of this research not all of the clinic sessions were fully booked; therefore patients could be seen very quickly. Increasing the number of patients transferred to the PCDS, or reducing the number of available appointments, would improve the efficiency of the PCDS but would probably negate one of its major advantages; that is, shorter waiting times.

Patients randomised to the hospital outpatient clinic were placed on the same waiting list as patients referred from other PCT areas. As discussed in Section 7.3.3, the patients transferred to the PCDS represented only 8% of all referrals to the BRI dermatology clinic, leading to little impact on overall workload or waiting times for an appointment at the hospital. If anything, the data on waiting times at trust level shown in Section 7.3 suggest that waiting times did not improve as much in the trust with the GPSI service as in neighbouring trusts.

In order to reduce waiting times it is important to match capacity to demand, after working off any backlog. If it is necessary to increase capacity, the evidence of this study suggests that the most efficient way to do this might be to provide more appointments at the hospital outpatient department rather than in a community clinic. These extra appointments might be provided by a GPSI working at the hospital, or in a number of other ways.

Pressure to reduce waiting times is one of the forces driving the expansion of GPSI roles. It is important to note that the discrete-choice modelling study showed that the quality of the consultation and the expertise of the doctor consulted were more important to patients than the wait for an appointment.

It is important to note that the relationship between supply, demand and waiting times is not straightforward. There has been a long history of attempts to understand the phenomenon of waiting lists in the NHS, and an equally long history of initiatives designed to reduce them, generally without conspicuous success. Martin *et al*. (2003) showed that there was no direct relationship between supply or need and waiting lists for inpatient care. Other authors have highlighted the range of factors that mitigate against attempts to reduce waiting lists (Cullis and Jones, 1985; Frankel, 1989; Iversen, 1993; Laing and Shiroyama, 1995; Street and Duckett, 1996). These include the impact of changing expectations of patients and of GPs acting as their agents, incentives for hospitals to maintain long waiting lists in order to attract extra resources, incentives for consultants to have long waiting lists to support private practice and as a mark of esteem, and the way in which resources are diverted by mangers towards or away from particular hospital departments when waiting times are deemed tolerable or excessive. In addition there are other factors which affect waiting times, not directly related to demand or capacity, such as poor organisation of appointment systems and the need to maintain a waiting list to maximise efficiency.

10.4.7 Reduced costs

There was no evidence from this study that establishing a GPSI is likely to lead to services being provided at a lower cost than in hospital, and in fact the reverse is true. This is consistent with previous research on consultant outreach clinics (Bowling and Bond, 2001; Powell, 2002). The main reason that the PCDS was more expensive than the hospital was because of the greater costs of staff time, and it is important to note that this partly reflects the fact that the PCDS was offering a different type of care from that provided by the hospital. Patients received longer consultations with the same doctor, rather than short consultations with a number of different doctors. Nurse consultations at PCDS were expensive because more patients in the PCDS arm saw a nurse, and they had lengthy consultations with a very experienced dermatology nurse, whereas many nurse consultations at the hospital were with nurses of lower grades.

In addition the PCDS was more expensive because all patients saw the relatively costly GPSI, whereas most of the care in hospital was provided by less costly staff-grade doctors and clinical assistants, rather than by the consultant. The enthusiasm from PCTs to introduce GPSI schemes, at the same time as many other initiatives are competing for GPs' time and GPs have experienced large increases in

income as a result of their new contract, may have led to inflationary pressures such that the pay rates of GPs are not competitive with those paid in hospitals. Furthermore, some PCTs have been paying locum fees for GPSIs as well as a salary (effectively paying them twice for the same period of time, if the GPSI continues to draw income from their practice), which will greatly increase the cost of GPSI services.

From the evidence of this study it does not appear that the expansion of GPSI roles can be justified on the basis of reducing costs, but the issue of cost can only be considered along with a consideration of the effect on outcomes.

If this scheme is typical, then those making the decision about whether the increased cost to the NHS of GPSI schemes is worth incurring must set the potential for using these funds to treat others who might benefit in terms of increased outcomes, against the benefits noted here in terms of increased access to care. The cost-effectiveness acceptability curve for the access scale suggests that, if prepared to pay £100 for an improvement in access of 10 points on this scale, the GPSI service would always be cost-effective. The important question in interpreting these figures is therefore to ask how much decision-makers are willing to pay to improve health care access, rather than spending funds on greater improvements in health outcome. Indeed, the scheme impacts on a number of outcomes, all of which decision-makers may wish to take into account.

Given the changing UK context in terms of the introduction in the NHS of the payment by results scheme (whereby PCTs will commission activity from hospitals based on a standard national price tariff; Department of Health, 2002a) it is useful to compare costs estimated in this research with those in the national tariff. Using the national tariff for dermatology outpatients, the mean cost of commissioning specialist care from a hospital for the patients in this study would have been £127 per patient (based on the new and follow-up consultation rates in the hospital arm), compared with £182 per patient actually spent in the GPSI arm (Department of Health, 2004c). Although PCTs are encouraged to shift resources to deliver services in new ways, particularly through the use of GPSIs (Department of Health, 2002a), these calculations illustrate the value that PCTs will need to place on the benefits of GPSI services to justify this extra investment.

The introduction of payment by results is likely to have a considerable effect on the future of GPSI services. They are only likely to survive if they can ensure their costs are at or below the tariff rate. At present some GPSI services may appear less expensive than the tariff but this may be because some costs which should be attributed to the GPSI service, such as premises, management and administration, consultant support, training and investigations, are being subsidised from other budgets or not charged at all. Payment by results is likely to lead to much greater transparency and organisations wishing to set up GPSI services will need to take account of all relevant costs.

10.4.8 Promoting skill mix

This study has shown the ability of doctors from a GP background with more limited specialist training than a consultant to manage a high proportion of patients referred to secondary care. Although (as noted above) one limitation of this research was that the important role of the specialist nurse in the PCDS could not be explored in depth, the model of two doctors working with a specialist nurse also appeared to be successful.

The expansion of GPSI services does illustrate the potential for re-considering the level at which care is best provided. It also provides further opportunities for career progression for both GPs and practice nurses, as discussed below. However, ultimately arguments in favour of increasing skill mix are mainly about improving the cost-effectiveness of care. Although GPSIs and specialist nurses are able to provide much of the care currently offered in hospitals this study suggests that this change is unlikely to be cost-effective, at least for models of care and settings similar to those in this study.

There are two separate issues: who should provide care and where should that care be provided? As discussed above, there are several groups of doctors (consultants, non-consultant-grade specialists, GPSIs) who could contribute to providing dermatology services for a high proportion of patients with relatively minor illness. Alternatively, one could envisage a service based on a much bigger role for nurses, which would be consistent with the move towards nurse-led services in NHS walk-in centres and chronic-disease-management programmes. Separate from this discussion is debate about where these professionals should be located. Outreach models with consultants working in primary care have not been successful, and GPSIs appear to be relatively expensive. An alternative model of skill mix may be for non-consultant grade dermatologists to work in community clinics. These doctors would not have the same level of management responsibility as consultants and GPs, and arguably would not necessarily need a greater level of specialist expertise than GPSIs to deal with a limited range of common problems, as in this study, and may achieve similar results at less cost than GPSIs.

10.4.9 Improve flexibility in GP careers, boosting recruitment and retention

Although not addressed by this research, one justification for the expansion of GPSI roles is that they enhance the job satisfaction and career opportunities of GPs, and hence aid recruitment and retention (Royal College of General Practitioners, Department of Health, 2002). There is some indirect evidence in support of this hypothesis, for example from a cross-sectional survey of GPSIs (Jones and Bartholomew, 2002), but no direct evidence. It is also important to consider the possibility that emphasising the opportunities for GPs to work as specialists may have subtle adverse effects (Royal College of

General Practitioners, 2004). It may reinforce the notion that generalist roles are less valuable than specialist roles, and encourage the perception of GPs as doctors who have 'fallen off the ladder', able to operate in a sub-consultant specialist role but not good enough to become consultant specialists. If the value of generalism is not strongly promoted, these perceptions may ultimately make recruitment to general practice more difficult (Royal College of General Practitioners, 2004).

10.5 Managerial issues and implications for PCTs

10.5.1 Guidance and resources

There are a large number of useful resources produced for PCTs considering establishing a GPSI service. This general guidance is not reiterated here, but Appendix 10 provides a bibliography of key resources.

After the PCDS had been open for about a year, a meeting of stakeholders was held to identify and discuss lessons that had been learnt locally about the establishment of a GPSI service. These are described in

Appendix 11.

10.5.2 Issues arising for consideration by local health care planners

The experience gained from the evaluation of the PCDS raised a number of issues of relevance to local health care planners, and these are discussed below. These comments are based not only on this evaluation but also on the findings from other relevant research.

- It is essential to have clear objectives before introducing a GPSI service. Is the objective to improve accessibility and convenience through a more local service, to provide a different type of service, to increase capacity in order to address unmet needs, to reduce waiting times, to reduce costs or to increase career opportunities for local GPs? Having discussions locally with all key stakeholders to reach clear agreement on these questions will help policy-makers determine whether a GPSI service is the best solution, informed by the evidence of this and other studies.
- GPSI services provide a more accessible and popular service, with no evidence to suggest that health outcomes are any better or worse than those obtained from outpatient care
- The location of the GPSI service is crucial. Some locations may be less accessible than the hospital alternative for many patients.
- Whether or how to triage referrals is a key decision. In this study, GPs made referrals as usual to the hospital clinic and letters were assessed to identify those patients suitable for the PCDS. This is probably the best way to reduce hospital waiting lists and ensure the appropriateness of patients seen at the hospital and GPSI clinic. A common alternative is to allow direct referral to the GPSI service, which may help to address unmet needs but may lead to increased total demand and have less impact on hospital waiting lists. This is related to the need for managers to be explicit about whether they intend the GPSI service to act as a substitute for the outpatient clinic or an additional service.
- Although patients seen at a GPSI clinic may have shorter waiting times than those seen at an outpatient clinic, introducing a GPSI service is unlikely to reduce waiting times by a significant degree at the hospital outpatient clinic because of the relative size and capacity of the two services.
- The appropriate size for a GPSI service is an important consideration. Small services with few staff are very vulnerable to staff sickness, and may be more costly. Larger services may overcome these problems, but need to draw patients from a larger area to be viable and therefore may be no more convenient and accessible for many patients than a hospital clinic.
- Introducing a GPSI service is likely to increase costs, both because each episode of care is likely to be more expensive and because the increased capacity may increase demand.

- Consider the appropriate skill-mix needed in relation to an audit of the range of cases to be managed. In particular, consider how much of the work should be done by specialist nurses or doctors. Also, consider whether it may be more cost-effective to employ non-consultant-grade dermatologists working in the community rather than GPSIs.
- In order to reduce waiting times for all patients it may be more efficient to increase capacity at the outpatient clinic, possibly by employing GPSIs, than to establish peripheral clinics.
- In order to maintain short waiting times for an appointment at the GPSI clinic it is important to have good data about the predicted demand based on historical trends and pilot studies. This study confirmed that it was possible to manage more than half of all non-urgent dermatology referrals in a GPSI clinic, and that triage using the referral letter was reasonably reliable, as only 12% of patients had to be subsequently referred to outpatients for follow-up.

10.6 Recommendations for future research

This study raises a number of issues which merit further research. The conclusions from this study apply only to one GPSI service in one clinical area, dermatology. Similar studies should be conducted in other areas and clinical specialities.

The question of whether providing extra capacity leads to increased demand is crucial to predicting the impact on waiting times, and has much wider relevance to the NHS beyond the question of GPSI services. Only limited evidence is available, mainly from observational studies, and this is open to various interpretations (see Section 10.4.5 for a discussion of some of the issues). With regard to GPSI services, this question could be addressed through randomising practices to have access to a new service, or by randomising areas to introduce a new service. The former is feasible whereas the latter is probably not. Although a clustered randomised controlled trial would be large and expensive to conduct, if the methodological difficulties could be surmounted this investment would be justified since the question is of such fundamental importance within the NHS.

Introducing GPSIs is only one way in which service capacity can be increased. Further studies should compare the costs and benefits of GPSIs with other models, such as increasing capacity in existing outpatient services.

It is not clear whether the benefits of the GPSI service relate to the type of professional or the community location of the service. Further studies should compare GPSIs located in hospitals with community clinics, and should compare different models of skill mix, such as employing specialist nurses or non-consultant dermatologists in the community rather than GPSIs.

The role of the specialist dermatology nurse in the Bristol PCDS was not examined in this study. Although similar roles have been explored in some small observational studies (Broberg *et al*., 1990; Ersser *et al.*, 1998; Van Onselen, 1998), this topic merits further research.

10.7 Conclusions

About half (49%) of all referrals to an outpatient dermatology service appeared to be suitable for management in the PCDS, based on the GP referral letter, and only 12% of these patients were subsequently referred on to the outpatient clinic.

There was no evidence that patients attending the PCDS obtained health outcomes which were markedly different from those attending the hospital outpatient service. Patients preferred to attend the PCDS, found it more accessible and were slightly more satisfied with their consultation compared with those attending the hospital outpatient service.

Patients offered appointments at the PCDS experienced much shorter waiting times than those offered appointments at the hospital outpatient service, but the extra capacity provided by the PCDS did not appear to lead to any reduction in dermatology outpatient waiting times.

Patients offered appointments at the PCDS were more likely to attend their first appointment, but overall DNA rates were not significantly different from those at the hospital outpatient clinic.

The benefits of the PCDS need to be balanced against the finding that the costs of this service to the NHS were considerably greater than the costs of hospital outpatient care. The costs of the PCDS for patients and their companions were slightly lower than for hospital care. The overall cost to society was higher for the PCDS than for hospital outpatient care.

Although the need to reduce outpatient waiting times is a key policy driver behind the expansion of GPSI services this does not appear to be the most important issue for patients. The thoroughness with which the consultation is provided and the expertise of the clinician seen are higher priorities.

There are probably important trade-offs to be made between the advantages and disadvantages of GPSI services exemplified by this study. It may be possible to reduce the costs associated with the GPSI service by increasing throughput, but this may involve losing the benefits of shorter waiting times and longer consultations leading to greater patient satisfaction. Alternatively, costs could probably be reduced by providing a GPSI service within a hospital outpatient setting to achieve economies of scale, but this may reduce the benefit of local accessibility. The relative importance of these issues of accessibility, waiting times and costs in relation to other GPSI services

is likely to be related to the context in terms of the geographical area and clinical topic.

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Appendices

Appendix 1 Questionnaire 1

Study of a Dermatology Service

Questionnaire 1 **Study ID number** ☐☐☐☐☐☐

1. How your skin affects your life

*The aim of this questionnaire is to measure how much your skin problem has affected your life **OVER THE LAST WEEK**. Please tick one box for each question.*

	Very much	A lot	A little	Not at all	Not relevant
a) Over the last week, how itchy, sore, painful or stinging has your skin been?	☐1	☐2	☐3	☐4	☐5
b) Over the last week, how embarrassed or self conscious have you been because of your skin?	☐1	☐2	☐3	☐4	☐5
c) Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?	☐1	☐2	☐3	☐4	☐5
d) Over the last week, how much has your skin influenced the clothes you wear?	☐1	☐2	☐3	☐4	☐5
e) Over the last week, how much has your skin affected any social or leisure activities?	☐1	☐2	☐3	☐4	☐5
f) Over the last week, how much has your skin made it difficult for you to do any sport?	☐1	☐2	☐3	☐4	☐5
g) Over the last week, has your skin prevented you from working or studying?	☐1	☐2	☐3	☐4	☐5
h) Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	☐1	☐2	☐3	☐4	☐5
i) Over the last week, how much has your skin caused any sexual difficulties?	☐1	☐2	☐3	☐4	☐5
j) Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	☐1	☐2	☐3	☐4	☐5

2. If, in the future, you had a choice, would you rather be seen at:
(please note this answer will not affect where you are actually sent an appointment)

1. the Hospital Outpatients Department at the Bristol Royal Infirmary ☐1

or

2. the Primary Care Dermatology Service at Knowle West Health Park ☐2

3. Please could you tell us why you would rather be seen there?

.....

Thank you. Please check you have answered every question, then return the questionnaire with the consent form in the reply paid envelope

Questionnaire 2. 16.12.02

6. Patient satisfaction questionnaire

We would like to know how satisfied you were with your appointment. Please answer the following questions as best you can.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
a) I am totally satisfied with my visit to this doctor / nurse	☐1	☐2	☐3	☐4	☐5
b) This doctor / nurse was very careful to check everything when examining me	☐1	☐2	☐3	☐4	☐5
c) I will follow this doctor's / nurse's advice because I think he/she is absolutely right	☐1	☐2	☐3	☐4	☐5
d) I felt able to tell this doctor / nurse about very personal things	☐1	☐2	☐3	☐4	☐5
e) The time I was able to spend with the doctor / nurse was a bit too short	☐1	☐2	☐3	☐4	☐5
f) This doctor / nurse told me everything about my treatment	☐1	☐2	☐3	☐4	☐5
g) Some things about my consultation with the doctor / nurse could have been better	☐1	☐2	☐3	☐4	☐5
h) There are some things this doctor / nurse does not know about me	☐1	☐2	☐3	☐4	☐5
i) I thought this doctor / nurse took notice of me as a person	☐1	☐2	☐3	☐4	☐5
j) The time I was allowed to spend with the doctor / nurse was not long enough to deal with everything I wanted	☐1	☐2	☐3	☐4	☐5
k) I understand my illness much better after seeing this doctor / nurse	☐1	☐2	☐3	☐4	☐5
l) This doctor / nurse was interested in me as a person not just in my illness	☐1	☐2	☐3	☐4	☐5
m) This doctor / nurse knows all about me	☐1	☐2	☐3	☐4	☐5
n) I felt this doctor / nurse really knew what I was thinking	☐1	☐2	☐3	☐4	☐5

3

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
o) I wish it had been possible to spend a little longer with the doctor / nurse	☐1	☐2	☐3	☐4	☐5
p) I am not completely satisfied with my visit to the doctor / nurse	☐1	☐2	☐3	☐4	☐5
q) I would find it difficult to tell this doctor / nurse about some private things	☐1	☐2	☐3	☐4	☐5
r) This doctor/nurse examined me very thoroughly	☐1	☐2	☐3	☐4	☐5

7. We would like to know what you thought of the place in which you were seen

Please answer the following questions as best you can

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not applicable
a) It was very easy to travel to my appointment	☐1	☐2	☐3	☐4	☐5	
b) It was very difficult to find a parking space	☐1	☐2	☐3	☐4	☐5	☐6
c) Finding where to go for my appointment was difficult	☐1	☐2	☐3	☐4	☐5	
d) It was easy to get public transport to my appointment	☐1	☐2	☐3	☐4	☐5	☐6
e) The receptionist was very polite and helpful	☐1	☐2	☐3	☐4	☐5	
f) I was very impressed with the waiting area.	☐1	☐2	☐3	☐4	☐5	
g) The room in which I was seen for my appointment was clean and pleasant	☐1	☐2	☐3	☐4	☐5	

Thank you. Please check you have answered every question, then return the questionnaire in the reply paid envelope.

4

Appendix 2 Questionnaire 2

Study ID number ☐☐☐☐☐☐☐

Questionnaire 2

Study of a Dermatology Service

1. Cost of travel to your appointment

We would like to find out how you travelled to this appointment and how much it cost you.

a) Did you travel by

- car / van ☐1
- taxi / train / bus ☐2
- on foot / by bicycle ☐3
- hospital transport ☐4
- motorbike/scooter ☐5

b) *If you travelled by car/van/motorbike*

b i) How many miles was the <u>return</u> journey? .....miles.

b ii) Did you have to pay to park? No ☐1 Yes ☐2 It cost £___:___p

c) *If you travelled by train, bus or taxi*, how much was the <u>return</u> fare? £___:___p

d) Were you able to claim back the cost of your journey?

- No ☐1
- Yes ☐2
- I hold a free bus pass ☐3

2. Time off work

a) Did you have to take time off work to attend your appointment?

- No ☐1 *please go to **question 3***
- Yes ☐2 *please answer questions below:*

b) How many *hours* did you have to take off work? .....

c) Were you paid during this time off?

- No ☐1
- Yes ☐2
- Self employed ☐3

3. Childcare or other dependant costs

Did you have to pay anyone to care for your child or other dependant during your visit?

No ☐1
Yes ☐2 *If yes*, how much did you pay? £____:____p

4. Companion costs

a) Did anyone accompany you to your appointment?

No ☐1 *please go to **question 5***
Yes ☐2 *please answer the questions below*

b) Did this person pay any bus/train fares?

No ☐1
Yes ☐2 How much was their return fare? £___:___p

c) Did this person lose any time off paid employment?

No ☐1
Yes ☐2 How many hours did they have to take off work? .....
Were they paid during this time off? No ☐1 Yes ☐2 Self employed ☐3

5. Cost of looking after your skin

We would like to find out how much it costs you to care for your skin. Many people have to buy things over the counter to help with their skin. Please answer the following questions as well as you can.

a) In the <u>two weeks before your appointment</u>, did you use any treatments bought over the counter, without a prescription?

No ☐1
Yes ☐2 I have spent £___:___p (*Please estimate if you cannot remember exactly*)

b) Do you pay prescription charges?

No ☐1
Yes ☐2 Do you have a pre-paid certificate? No ☐1 Yes ☐2

c) Since you agreed to take part in the study have you had any consultations for your skin condition with doctors, herbalists, homeopaths or any other person which you had to pay for privately (that is not as part of the NHS) ?

No ☐1
Yes ☐2

If yes, which of the following practitioners have you seen?

Specialist	No	Yes	Number of times	Cost per visit
a) Private Doctor	☐1	☐2		
b) Homeopath	☐1	☐2		
c) Acupuncturist	☐1	☐2		
d) Herbalist	☐1	☐2		
e) Reflexologist	☐1	☐2		
f) Aromatherapist	☐1	☐2		
g) Faith healer	☐1	☐2		
h) Other (please specify)	☐1	☐2		

Appendix 3 Questionnaire 3

Questionnaire 3. 16.12.02.

Study of a Dermatology Service

Questionnaire 3 **Study ID number** ☐☐☐☐☐☐

1. How your skin affects your life

*The aim of this questionnaire is to measure how much your skin problem has affected your life **OVER THE LAST WEEK**. Please tick one box for each question.*

	Very much	A lot	A little	Not at all	Not relevant
a) Over the last week, how itchy, sore, painful or stinging has your skin been?	☐¹	☐²	☐³	☐⁴	☐⁵
b) Over the last week, how embarrassed or self-conscious have you been because of your skin?	☐¹	☐²	☐³	☐⁴	☐⁵
c) Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?	☐¹	☐²	☐³	☐⁴	☐⁵
d) Over the last week, how much has your skin influenced the clothes you wear?	☐¹	☐²	☐³	☐⁴	☐⁵
e) Over the last week, how much has your skin affected any social or leisure activities?	☐¹	☐²	☐³	☐⁴	☐⁵
f) Over the last week, how much has your skin made it difficult for you to do any sport?	☐¹	☐²	☐³	☐⁴	☐⁵
g) Over the last week, has your skin prevented you from working or studying?	☐¹	☐²	☐³	☐⁴	☐⁵
h) Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	☐¹	☐²	☐³	☐⁴	☐⁵
i) Over the last week, how much has your skin caused any sexual difficulties?	☐¹	☐²	☐³	☐⁴	☐⁵
j) Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	☐¹	☐²	☐³	☐⁴	☐⁵

	Much worse	Slightly worse	No change	Slightly better	Much better
k) Overall, has your skin condition improved since your appointment?	☐¹	☐²	☐³	☐⁴	☐⁵

Thank you. Please check you have answered every question and then return the questionnaire in the reply paid envelope

1

Appendix 4 Questionnaire 4

Study number

Study of a Dermatology Service

HOW YOUR SKIN AFFECTS YOUR LIFE

1. The aim of this question is to measure how much your skin problem has affected your life over the last week. *(Please tick one box for each question)*

	Very much	A lot	A little	Not at all	Not relevant
a) Over the last week, how itchy, sore, painful or stinging has your skin been?	☐1	☐2	☐3	☐4	☐5
b) Over the last week, how embarrassed or self-conscious have you been because of your skin?	☐1	☐2	☐3	☐4	☐5
c) Over the last week, how much has your skin interfered with going shopping or looking after your home or garden	☐1	☐2	☐3	☐4	☐5
d) Over the last week, how much has your skin influenced the clothes you wear?	☐1	☐2	☐3	☐4	☐5
e) Over the last week, how much has your skin affected any leisure activities?	☐1	☐2	☐3	☐4	☐5
f) Over the last week, how much has your skin made it difficult for you to do any sport?	☐1	☐2	☐3	☐4	☐5
g) Over the last week, has your skin prevented you from working or studying?	☐1	☐2	☐3	☐4	☐5
h) Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	☐1	☐2	☐3	☐4	☐5
i) Over the last week, how much has your skin caused any sexual difficulties?	☐1	☐2	☐3	☐4	☐5
j) Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	☐1	☐2	☐3	☐4	☐5

	Much worse	Slightly worse	No change	Slightly better	Much better
k) Overall has your skin condition improved since you agreed to take part in this study?	☐1	☐2	☐3	☐4	☐5

COST OF LOOKING AFTER YOUR SKIN

We would like to find out how much it costs you to care for your skin. Many people have to buy things over the counter to help with their skin. Please answer the following question as well as you can.

2. In the last two weeks, have you used any treatments bought over the counter, without a prescription?

No ☐1
Yes ☐2 **I have spent £____.____p**
(If you cannot remember exactly an estimate will do)

3. Since your first visit to either the outpatient dermatology department at the BRI or the primary care dermatology service, have you had any consultations for your skin condition with doctors, herbalists, homeopaths or any other person, which you had to pay for privately (that is, not as part of the NHS)?

No ☐1 → ***please go to question 4***
Yes ☐2 → ***please complete Table A below***
Did not attend dermatology appointment ☐3 → *If you were not able to attend your dermatology appointment for any reason, have you paid for any private treatment since you agreed to take part in the study?*
No ☐4 → *please go to question 4*
Yes ☐5 → *please complete Table A below*

Table A: Which of the following practitioners have you seen? *Please tick no or yes for each practitioner*

Specialist	No	Yes	Number of times	Cost per visit
a) Private Doctor	☐1	☐2		
b) Homeopath	☐1	☐2		
c) Acupuncturist	☐1	☐2		
d) Herbalist	☐1	☐2		
e) Reflexologist	☐1	☐2		
f) Aromatherapist	☐1	☐2		
g) Faith healer	☐1	☐2		
h) Other (please specify)	☐1	☐2		

VISITS TO YOUR GP SURGERY

In questions 4 to 8 please only include normal visits to your GP practice and do not include any visits to the Primary Care Dermatology service.

4. Since you agreed to take part in the study, have you visited a GP or practice nurse, because of your skin condition?

No ☐1 → *please go to question 9*

Yes ☐2 → how many visits? .....

5. Cost of travel to the GP surgery

a) Do you usually travel by

car / van ☐1
taxi / train / bus ☐2
on foot / by bicycle ☐3
hospital transport ☐4
motorbike / scooter ☐5

b) *If you travelled by car, van or motorbike*

i) How many miles was the return journey? .....miles

ii) Did you have to pay to park?

No ☐1
Yes ☐2 It cost £____.____p

c) *If you travelled by train, bus or taxi*

i) how much was the return fare? £____.____p

6. Time off work to attend GP or practice nurse appointments

a) Since you agreed to take part in the study have you had to take time off work to visit your GP surgery about your skin condition?

No ☐1 → *please go to question 7*
Yes ☐2

b) How many hours in total did you have to take off work? ..... hours

c) Were you paid during this time off?

No ☐1
Yes ☐2
Self employed ☐3

7. Companion costs to attend GP surgery

a) Did anyone accompany you on these visits to the surgery?

No ☐1 → *please go to question 8*
Yes ☐2 → *please answer the questions below*

b) Did this person pay any bus/train fares?

No ☐1
Yes ☐2 *if yes*, how much was their return fare?

£____.____p

c) Did this person lose any time off paid employment?

No ☐1
Yes ☐2 *if yes*, how many hours did they have to take off work in total?

..... hours

d) Were they paid during this time off?

No ☐1
Yes ☐2
Self employed ☐3

8. Child care or other dependant costs

Did you have to pay anyone to care for your child or other dependant during your visit(s) to the GP surgery?

No ☐1
Yes ☐2 *If yes*, how much did you pay?

£____.____p

VISITS FROM YOUR DISTRICT NURSE

9. Since you agreed to take part in the study, have you been visited by a district nurse, because of your skin condition?

No ☐1
Yes ☐2

FOLLOW UP VISITS

10. Please tell us where you had your first dermatology appointment since you agreed to take part in this study

a) Primary Care Dermatology Service at William Budd Health Centre ☐1 → *please go to question 11*

b) BRI Dermatology Outpatients ☐2 → *go to question 16, on the last page*

c) Please tick this box if you have **not** attended any appointments for your skin since agreeing to take part in the study ☐3 → *go to question 16, on the last page*

11. If you had your first appointment at the Primary Care Dermatology Service:

Since your first visit to the Primary Care Dermatology Service at Knowle West, have you attended the Outpatient Dermatology Department at the BRI?

No ☐1 → *go to question 16, on the last page*

Yes ☐2 → *please answer the next questions:*

12. Cost of travel to your BRI appointment(s)

a) When you visit the BRI, do you usually travel by

car / van ☐1
taxi / train / bus ☐2
on foot / by bicycle ☐3
hospital transport ☐4
motorbike / scooter ☐5

b) ***If you travel by car, van or motorbike***

i)How many miles is the <u>return</u> journey? …….. miles.

ii)Do you have to pay to park?

No ☐1
Yes ☐2 **It costs** £____.____p

c) ***If you travel by train, bus or taxi***

i) How much is the <u>return</u> fare? £____.____p

d) Are you are able to claim back the cost of your journey(s)?

No ☐1
Yes ☐2
I hold a free bus pass ☐3

13. Time off work to attend your BRI appointment(s)

a) Have you had to take <u>time off work</u> to attend these appointment(s) at the BRI about your skin condition?

No ☐1 → *please go to question 14*

Yes ☐2 → *please answer the questions below*

b) How many hours <u>in total</u> did you have to take off work? …….. hours

c) Were you paid during this time off?

No ☐1
Yes ☐2
Self employed ☐3

14. Companion costs to attend BRI appointments

a) Did anyone accompany you to these appointment(s) at the BRI?

No ☐1 → *please go to question 15*

Yes ☐2 → *please answer the questions below*

b) Did this person pay any bus/train fares?

No ☐1
Yes ☐2 ***if yes*, how much have they paid in total?**

£____.____p

c) Did this person lose any time off paid employment?

No ☐1
Yes ☐2 ***if yes*, how many hours did they have to take off work <u>in total</u>?**

…….. hours

d) Were they paid during this time off?

No ☐1
Yes ☐2
Self employed ☐3

15. Child care or other dependant costs

Did you have to pay anyone to care for your child or other dependant during your visit (s) to the BRI ?

No ☐1
Yes ☐2 ***If yes*, how much did you pay?**

£____.____p

FUTURE CHOICE OF SERVICE

16. a) If, in the future, you had a choice, would you rather be seen at:

Hospital Outpatients Department at the Bristol Royal Infirmary ☐1

or

Primary Care Dermatology Service at Knowle West Health Park ☐2

b) Please could you tell us why you would rather be seen there?

.....

.....

.....

.....

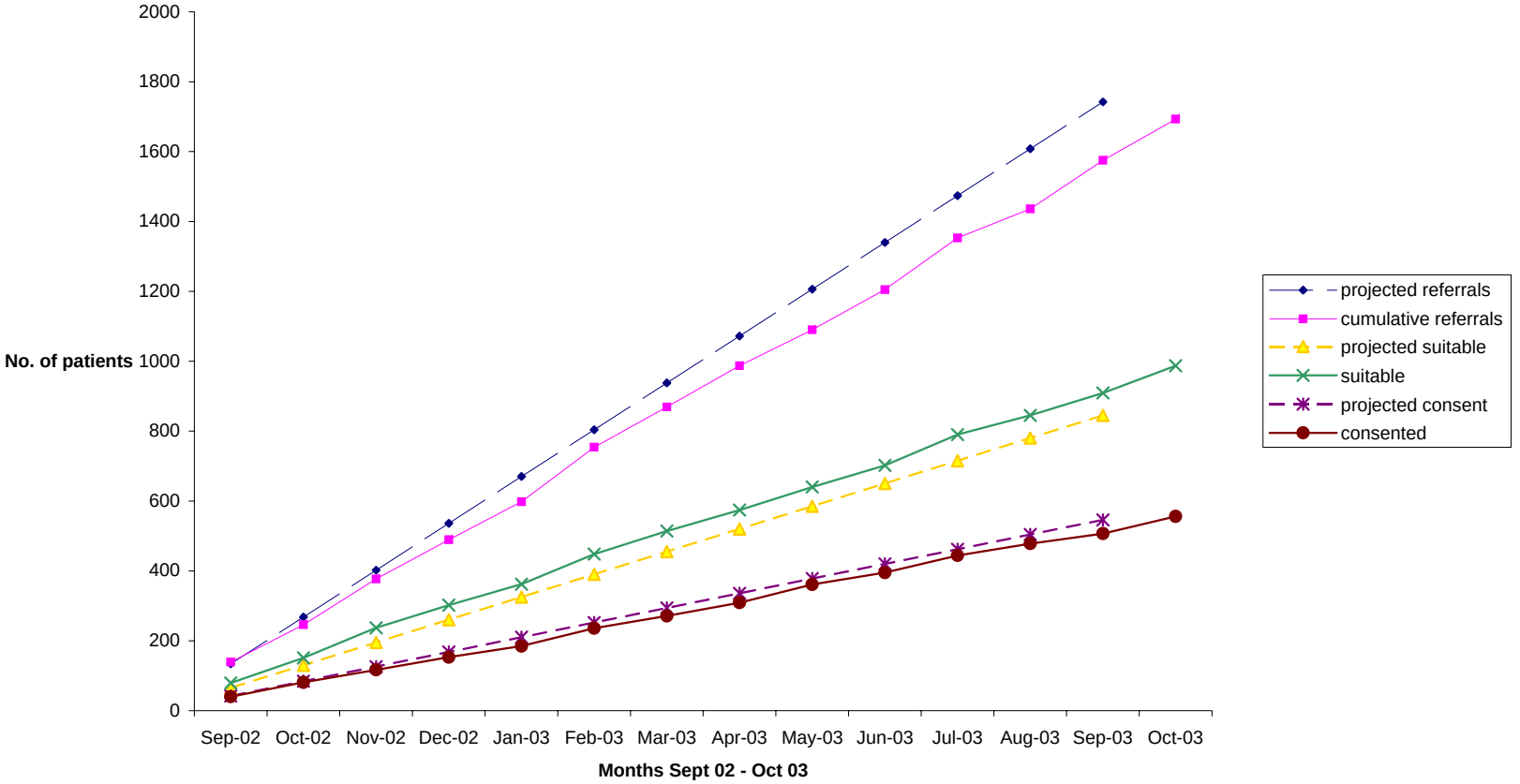
Thank you for your help

Please check you have answered every question, then return the questionnaire in the reply paid envelope

If you have any problems with completing this questionnaire please contact the Research Co-ordinator, Sue Horrocks 0117- 9546686

Division of Primary Health Care, University of Bristol
Cotham House, Cotham Hill, Bristol BS6 6JL

Appendix 5 Recruitment rates in relation to targets



Appendix 6 Randomisation by practice

Practice	Total referrals by practice (*n*=1693)	No. all suitable (*n*=987; %)	No. suitable patients contacted (*n*=768)	No. suitable patients contacted who gave consent (*n*=556/768; %)	No. at the PCDS (*n*=354; %)	No. at BRI (*n*=202; %)
L81006	67	34 (51)	32	28 (87)	20 (71)	8 (29)
L81007	62	45 (73)	31	23 (74)	15 (65)	8 (35)
L81009	97	57 (59)	49	42 (86)	28 (67)	14 (33)
L81031	64	42 (66)	34	28 (82)	17 (61)	11 (39)
L81032	59	39 (66)	31	26 (84)	17 (65)	9 (35)
L81033	70	42 (60)	37	28 (76)	18 (64)	10 (36)
L81035	62	38 (61)	31	22 (71)	15 (68)	7 (32)
L81041	34	19 (56)	14	12 (86)	6 (50)	6 (50)
L81053	101	51 (50)	42	36 (86)	24 (67)	12 (33)
L81054	33	14 (42)	11	8 (73)	6 (75)	2 (25)
L81057	79	40 (51)	29	21 (72)	14 (67)	7 (33)
L81081	71	44 (62)	36	22 (61)	15 (68)	7 (32)
L81082	52	33 (63)	23	20 (87)	13 (65)	7 (35)
L81083	64	44 (69)	35	23 (66)	16 (69)	7 (31)
L81084	91	49 (54)	43	33 (77)	22 (67)	11 (33)
L81090	99	56 (57)	42	24 (57)	16 (67)	8 (33)
L81091	173	115 (66)	84	36 (43)	20 (55)	16 (45)
L81093	31	17 (55)	14	10 (71)	6 (60)	4 (40)
L81094	48	27 (56)	18	15 (83)	9 (60)	6 (40)
L81095	14	8 (57)	6	5 (83)	3 (60)	2 (40)
L81096	43	23 (53)	13	11 (85)	7 (64)	4 (36)
L81115	62	26 (42)	21	20 (95)	13 (65)	7 (35)
L81120	70	47 (67)	38	27 (71)	15 (55)	12 (45)
L81125	46	25 (54)	22	17 (77)	10 (59)	7 (41)
L81133	59	26 (44)	14	7 (50)	3 (43)	4 (57)
L81633	4	4 (100)	1	1 (100)	-	1 (100)
L81640	14	8 (57)	8	5 (62)	2 (40)	3 (60)
L81656	17	11 (65)	7	4 (57)	3 (75)	1 (25)
L81666	4	2 (50)	2	2 (100)	1 (50)	1 (50)

Missing practice details	3	1	0	–	–

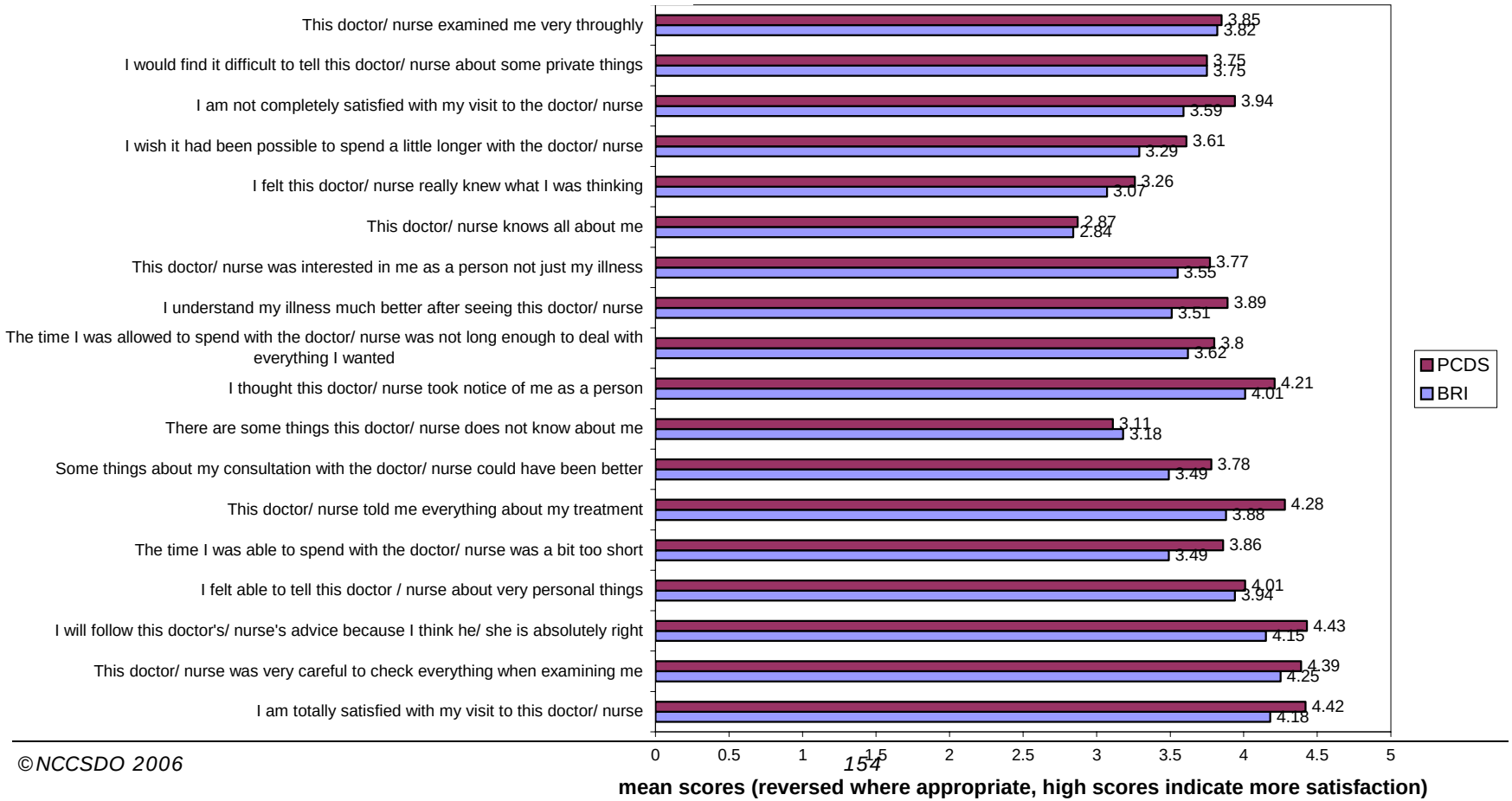
Appendix 7 Access and facility scales

	Factor loading value	**Cronbach's alpha**
Access scale		
It was easy to travel to my appointment	0.60	0.64
It was difficult to find a parking space	0.51	
Finding where to go for my appointment was difficult	0.54	
Facilities scale		
The receptionist was very polite and helpful	0.60	0.78
I was impressed with the waiting area	0.69	
The room in which I was seen for my appointment was clean and pleasant	0.68	
Question not contributing		
It was easy to get public transport to my appointment		

Appendix 8 Further details of questions included in CSQ and facilities scales

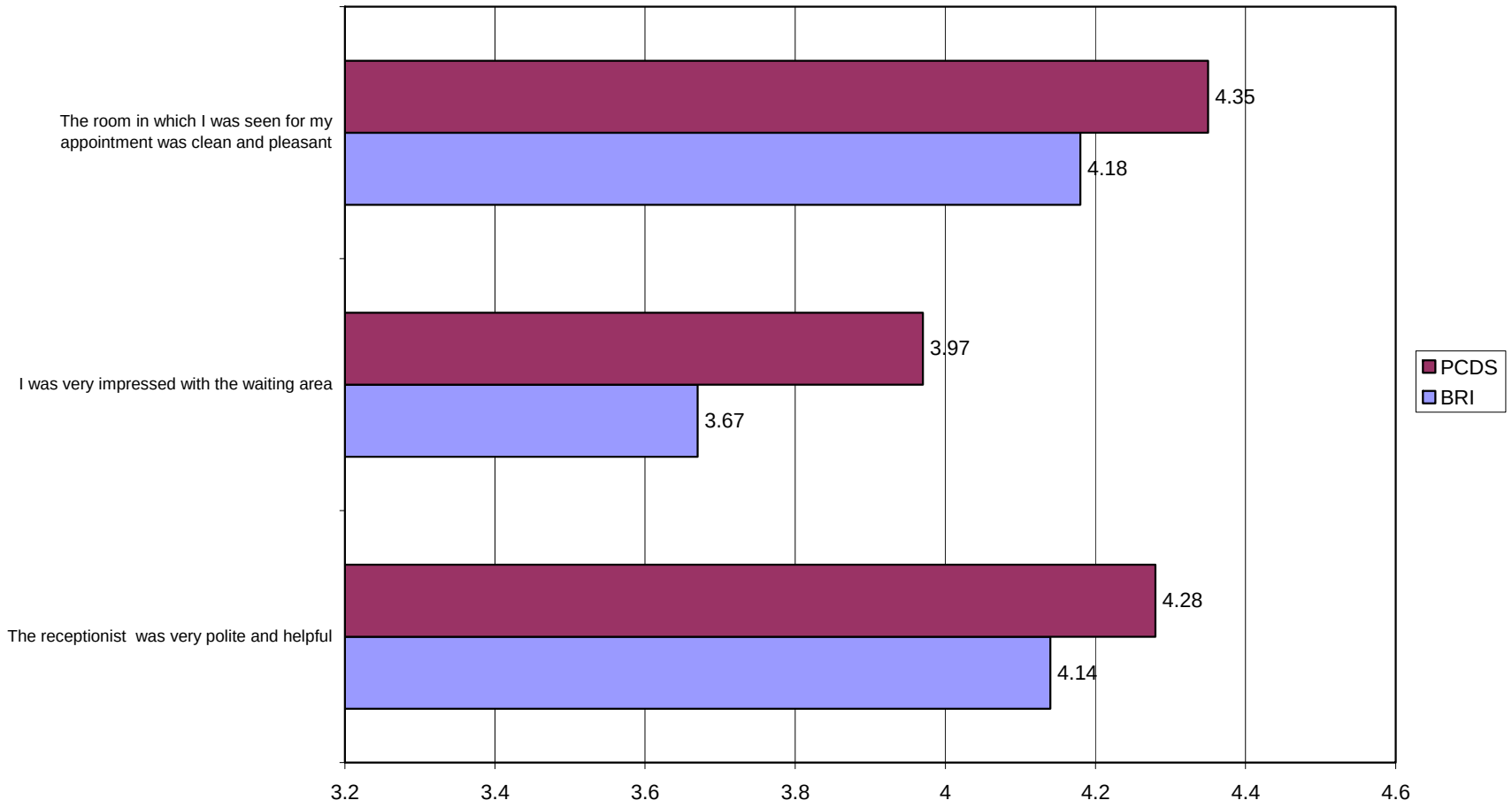
This table shows the mean scores for each statement, where 1=strong agreement and 5=strong disagreement. Where statements were negatively worded, the scores have been reversed so that high scores consistently indicate greater satisfaction.

Consultation satisfaction questionnaire



Mean scores on questions contributing to facilities scale

Higher scores indicate more satisfaction.



Appendix 9 Interview schedule

Note: exact content and order were varied according to responses.

1 Can we start with talking about the time when you first had the problem with your skin (name of condition)?

Further probes to explore participant's perception of the severity of the skin condition, the amount of trouble they are having, understandings about the condition and the assistance offered and received in terms of health and social care.

2 What (if any) sort of problems did you experience in getting help (with your skin condition)?

This will identify common problems experienced by patients accessing services.

3 How much improvement to your skin are you expecting as a result of your GP referring you to the hospital?

This will probe the extent to which a good clinical outcome is important for the success of the consultation.

4 If it were possible to *choose* where you received your care, between a hospital location and a local setting such as a health centre, where would you want to receive it? Why?

This question will explore aspects of care and access considered important by the interviewee. Probes will explore importance of pros and cons raised by the patient.

5 What do you like about getting care from the hospital?

e.g. Will probe the perceived importance of specialist equipment, consultant or specialist care and importance of location.

6 What don't you like about getting care from the hospital?

Probes will check the length of time thought acceptable to wait for an appointment, the length of waiting time once a patient has presented for an appointment, transport links and ease of parking.

7 Some people may be able to receive their care from a specialist GP and nurse at a local health centre. What do you like about that idea?

8. What *don't* you like about that idea?

Questions added to help define and refine attributes associated with access to health care identified by earlier informants, after 15 interviews had been carried out, as follows.

- Some people have told us that the most important thing about getting care for their skin complaint is the convenience of the service. What do you think they would mean by 'convenience'? Would 'easy to get to' be another way of talking about convenience?
- What would you understand by a service being 'difficult to get to'?
- How important to you are the other facilities that might be available in the same place i.e. coffee machines, or local café or dispensary?
- What about the wait to see the doctor once you get there? Some people have told us they tend to expect to wait and are prepared for it. How do you feel about waiting once you arrive for your appointment? Is it important to you? If

you could choose where you had your care, would the wait for your appointment be an important issue for you to consider?

- Some people have told us the most important thing about their care is the opportunity to see an expert, whilst others have said the quality of their consultation is the most important thing. I was wondering what you would think about these ways of describing a good consultation: a doctor who 'takes the trouble', 'shows real interest', is 'a bit more personal', who 'pays attention', 'listened to me', 'no rush', 'really interested in me'.

Appendix 10 Electronic resources and guidance about GPSI services

All URLs were correct on 18 April 2005.

GPSIs generally

- National Primary and Care Trust Development Programme website on GPSIs

http://www.natpact.nhs.uk/cms.php?pid=165

- A list of useful documents

http://www.natpact.nhs.uk/cms/352.php

- A step-by-step guide to setting up a GPSI scheme locally

http://www.natpact.nhs.uk/uploads/PDF%20-%20Step%20by%20Step%20Final%20pdf%20version.pdf

- 'Wizards' from the Modernisation Agency on improving access and reducing waiting times

http://www.natpact.nhs.uk/uploads/PDF%20Little%20Wizard.pdf

http://www.natpact.nhs.uk/uploads/BigWizard_1.1_full.pdf

- Managing risk

http://www.natpact.nhs.uk/uploads/PWSIManagingRisks.doc

- Practitioners with a special interest: frequently asked questions

http://www.gpwsi.org/faq/index.htm

- Practitioners with special interests in primary care: implementing a scheme for nurses in primary care (*Liberating the talents*; Department of Health, 2003).

http://www.dh.gov.uk/assetRoot/04/06/92/07/04069207.pdf

- Implementing a scheme for general practitioners with special interests (Department of Health, Royal College of General Practitioners, 2002).

http://www.dh.gov.uk/assetRoot/04/05/98/61/04059861.pdf

- Practitioners with special interests: bringing services closer to patients (Department of Health, 2003).

http://www.dh.gov.uk/assetRoot/04/07/23/69/04072369.pdf

- Guidelines for the appointment of GPSIs: Generic Model (Department of Health, 2002).

http://www.dh.gov.uk/assetRoot/04/05/98/62/04059862.pdf

- Quicker treatment closer to home. Primary care trusts' success in redesigning care pathways (Audit Commission, 2004).

www.audit-commission.gov.uk/pct/treatment.asp

- Action of Dermatology

http://www.modern.nhs.uk/scripts/default.asp?site_id=30&id=2712

- Ten Top Tips for Dermatology

http://www.modern.nhs.uk/serviceimprovement/1339/1988/7626/Top%20Ten%20Tips%20for%20Dermatology%20final.doc

- Guidelines for the appointment of GPSIs in the delivery of clinical services: dermatology.

http://www.natpact.nhs.uk/uploads/PDF%20Dermatology.pdf

- British Association of Dermatologists Position Statement on GPs with a Special interest in dermatology.

http://www.bad.org.uk/healthcare/service/statement.asp

Appendix 11 Barriers and facilitators to the success of setting up the PCDS: findings from a meeting of stakeholders

Facilitators and things that worked well

Budget issues

Having clearly defined fixed funding for the service meant it was not an issue. Therefore more attention could be spent on developing and setting up the service.

Location

The location of the GPSI service was crucial, if it is going to be accessible to a high proportion of the relevant population. Some locations may be less accessible than the hospital.

Host practice

There must be enough space within the host practice to be able to offer all the services, as well as room for the staff. Cooperation and good communication is important and this must be continuous throughout setting up and running the service.

Manager of the project

Identifying and recruiting a lead manager to oversee the development of the project and agree management arrangements worked well. The project manager and lead consultant needed dedicated time – for both it was a large time commitment on top of already busy jobs.

Relationships

In this instance good relationships existed between the PCT manager, the consultant and the key GPs. In setting up this type of service constructive relationships and trust need to exist between the primary- and secondary-care trusts, as developing a primary-care-based specialist service potentially raises threats as well as opportunities for key stakeholders.

Integration with secondary care

Related to the above point, the PCDS is strongly integrated with the secondary-care service. This is due to several factors: referrals are all made via the secondary-care service; leadership is provided by one of the consultant dermatologists; all the primary-care clinicians have previously worked in the secondary-care clinic; continuing education for the primary-care clinicians happens via the consultant. This close integration was seen as a great strength in ensuring the success of the PCDS.

Start on time

Starting the project on time was achieved successfully due to good planning and having a clear project plan.

Commitment

It is crucial to have the full commitment of all staff involved with setting up the service. Having the consultant's time and full support was particularly important.

Triaging of referral

Being aware of and being able to deal with the potential demand on the service was important. It was crucial to have strict criteria for who was eligible and then to stick to them.

Clinical lead

Having a clinical lead for the first few weeks with no patient caseload worked well. This helped with sorting out any practical problems that were encountered.

Administrative support

It was helpful to have a member of staff working at the PCDS who had a background in secondary-care administrative processes. It was important to have administrative staff in place before the service began, with well-defined job descriptions. It was also important to have regular meetings to aid communication.

IT issues

It was very helpful to run the PCDS using the EMIS general practice computer software, as the GPSIs were familiar with this, it manages templates well to enable protocol-driven care and structured data recording, and it was easily 'bolted on' to the existing computer system in operation in the health centre hosting the PCDS. Issues such as the electronic downloading of pathology results had already been resolved. The PCDS was therefore effectively paperless, with all clinical records being made into the EMIS software.

Good publicity

Publicising the new service well was gained by giving presentations at GP forums and Community Practitioner Forums.

Process mapping

It was very helpful to establish a detailed process map early in the planning process. This explained in detail the exact process through which referrals were managed.

Protocols

Protocols for many aspects of the PCDS were devised and reflected in clinical templates in the EMIS system.

Patients

Although the planning team for the PCDS sought to get patients involved in planning the service it was difficult to achieve this, even in an area which has a long-term commitment to patient involvement. It was helpful to walk through the new service as an actual patient to see what exactly is involved with making an appointment. This identified issues in relation to reporting to reception and signposting of the service

Barriers and things that worked less well

Conflicts between needs of the service and the research

The fact that the PCDS was being established in the context of a randomised trial meant that fewer people were being referred to the PCDS than had originally been planned. The need to reduce waiting times at the hospital was a major driver for the development of the primary-care-based service, which led to a conflict between the needs of the service and the needs of the research. Randomisation procedures were therefore changed to randomise two patients to PCDS for every one patient randomised to the hospital. In addition for every patient randomised in the trial to go to the hospital, a replacement patient from outside the area recruiting to the trial was transferred from the hospital to PCDS. In this way, the primary-care service saw as many patients as it would have done if the trial had not taken place. This also ensured that the research evaluated the PCDS under a typical patient load.

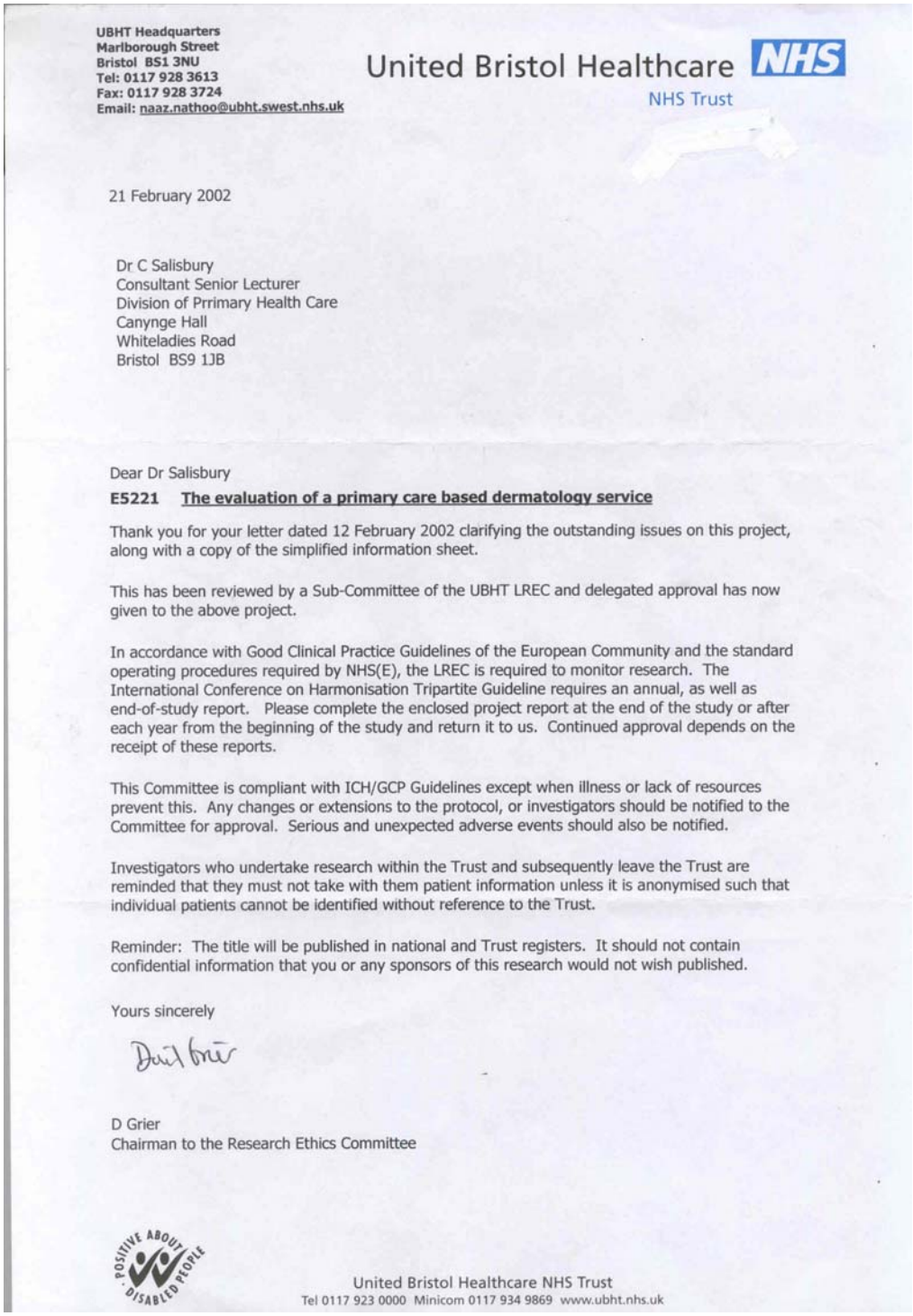
Information technology issues

Having the right technology and computer access is vital when setting up a new service. Making sure that the right people have been contacted to set up the computers and accessing the correct systems are important. Having these in place before the service is up and running can save a lot of time. The key issues are to decide on the services requirements, in terms of Internet access and shared folders and access to laboratory results, and to have all PCs set up in a standard way with templates to assist with GP letters and data collection in the clinical consultation.

Vulnerability of a small service

Because the PCDS is small, with few staff, the absence of any one of these staff seriously threatens the viability of the service. This occurred when one member of staff had a lengthy period of absence following an accident. A larger unit such as an outpatient department is less vulnerable to this type of eventuality.

Appendix 12 Ethics approval letter



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Email: naaz.nathoo@ubht.swest.nhs.uk

United Bristol Healthcare NHS
NHS Trust

21 February 2002

Dr C Salisbury
Consultant Senior Lecturer
Division of Prrimary Health Care
Canynge Hall
Whiteladies Road
Bristol BS9 1JB

Dear Dr Salisbury

E5221 The evaluation of a primary care based dermatology service

Thank you for your letter dated 12 February 2002 clarifying the outstanding issues on this project, along with a copy of the simplified information sheet.

This has been reviewed by a Sub-Committee of the UBHT LREC and delegated approval has now given to the above project.

In accordance with Good Clinical Practice Guidelines of the European Community and the standard operating procedures required by NHS(E), the LREC is required to monitor research. The International Conference on Harmonisation Tripartite Guideline requires an annual, as well as end-of-study report. Please complete the enclosed project report at the end of the study or after each year from the beginning of the study and return it to us. Continued approval depends on the receipt of these reports.

This Committee is compliant with ICH/GCP Guidelines except when illness or lack of resources prevent this. Any changes or extensions to the protocol, or investigators should be notified to the Committee for approval. Serious and unexpected adverse events should also be notified.

Investigators who undertake research within the Trust and subsequently leave the Trust are reminded that they must not take with them patient information unless it is anonymised such that individual patients cannot be identified without reference to the Trust.

Reminder: The title will be published in national and Trust registers. It should not contain confidential information that you or any sponsors of this research would not wish published.

Yours sincerely

D Grier
Chairman to the Research Ethics Committee

POSITIVE ABOUT DISABLED PEOPLE

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Addendum

This document was published by the National Coordinating Centre for the Service Delivery and Organisation (NCCSDO) research programme, managed by the London School of Hygiene & Tropical Medicine.

The management of the Service Delivery and Organisation (SDO) programme has now transferred to the National Institute for Health Research Evaluations, Trials and Studies Coordinating Centre (NETSCC) based at the University of Southampton. Prior to April 2009, NETSCC had no involvement in the commissioning or production of this document and therefore we may not be able to comment on the background or technical detail of this document. Should you have any queries please contact sdo@southampton.ac.uk.