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A randomised controlled crossover trial of nurse practitioner versus doctor-led outpatient care in a bronchiectasis clinic

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NHS R&D HTA Programme

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List of abbreviations

CI	confidence interval
CRIQ	Chronic Respiratory Index questionnaire
CT	computed tomography
FEV_1	forced expiratory volume in 1 second
FVC	forced vital capacity
GP	general practitioner
RCT	randomised controlled trial
SD	standard deviation
SF-36	Short Form 36 Health Survey
UKCC	UK Central Council for Nursing, Midwifery and Health Visiting

Executive summary

Objectives

In the setting of a specialist outpatient clinic for bronchiectasis patients, the study objectives were:

- to assess the feasibility and safety of nurse practitioner-led outpatient clinics and their acceptability to patients and their doctors
- to compare the cost-effectiveness of nurse practitioner-led care with a doctor-led system of care.

Design

The study was in two phases. In the first, the nurse practitioner completed a 6-month training programme to enable her to practise independently. This included tuition in the principles of bronchiectasis and its clinical presentation and management, together with practical experience and skills in clinical assessment and therapeutics. In the second phase, a randomised controlled trial of crossover design was used to compare nurse practitioner-led with doctor-led care in a bronchiectasis outpatients' clinic. Sample size was calculated on the basis of establishing equivalence of the two modes of care.

Setting

The lung defence clinic was introduced at Papworth Hospital in 1995 as a specialist unit with the purpose of streamlining the management of patients with bronchiectasis. Individual management plans are developed for intensive treatment and prophylaxis of endobronchial sepsis. Following initial investigation, patients with minor disease are followed-up in their local hospitals, returning to the specialist clinic annually for review. Patients with moderate to severe disease are seen in the specialist clinic several times a year.

It was in this context that the medical team considered the possibility of expanding the nurse practitioner's role to include outpatient follow-up of bronchiectasis patients. The medical team comprised three consultants and one rotating registrar with 2–3 years' experience of respiratory medicine.

Participants

Bronchiectasis is a chronic, usually progressive, respiratory disease characterised by dilatation and thickening of the bronchi. Patients experience repeated episodes of infection, chronic sputum production and increasing breathlessness, which ultimately progress to respiratory failure. The patients included in the study were over 18 years of age with moderate or severe bronchiectasis confirmed by high-resolution computed tomography scans. A treatment plan was formulated before a patient was considered eligible for the trial. The nurse practitioner did not assess new patients independently.

Interventions

Eighty patients were recruited and for the first year of the study were randomised to receive either 1 year of nurse practitioner-led care or 1 year of doctor-led care. The two groups then crossed over to receive the alternate mode of care for a further year. It was important that patients received each mode of care for a full year since chronic lung disease is subject to seasonal variation.

Main outcome measures

The primary outcome measure was lung function as measured by forced expiratory volume in 1 second (FEV_1). Patients were stratified as stable (decline in FEV_1 over the preceding 12 months < 5%) or unstable (decline in FEV_1 in the preceding 12 months ≥ 5%) prior to randomisation.

Secondary measures included walking distance, health-related quality of life, nurse practitioner autonomy, patient and general practitioner satisfaction with communications and care, patient compliance with treatment and resource use.

Results

Of the 80 patients recruited, 39 were randomised to nurse practitioner-led followed by doctor-led

care, and 41 to doctor-led followed by nurse practitioner-led care. The patients' mean age at randomisation was 58 years and 69% of them were female. Baseline lung function and 12-minute walk distance were similar in the two groups.

At the final follow-up, the mean difference in FEV_1 between nurse practitioner-led and doctor-led care was 0.2% predicted (95% confidence interval (CI), –1.6 to 2.0; $p = 0.83$). The mean difference in 12-minute walk distance between the two methods of service delivery was 18 metres (95% CI, –13 to 48; $p = 0.30$). The number of infective exacerbations experienced by patients during nurse practitioner-led care was 262 in 79.4 patient-years of follow-up, compared with 238 in 77.8 years during doctor-led care. Thus, nurse practitioner-led care resulted in a relative rate of exacerbation of 1.09; however, the difference was not statistically significant (95% CI, 0.91 to 1.30; $p = 0.34$). Of those patients who were using antibiotics and indicated their compliance, 100% were compliant (95% CI, 89 to 100) while receiving nurse practitioner-led care compared with 81% (95% CI, 63 to 93) of patients during doctor-led care, a difference that was statistically significant ($p = 0.024$).

The health-related quality-of-life analysis revealed no significant mode of care effects. However, patients reported less vitality/energy and greater levels of pain following doctor-led care but fewer role limitations because of emotional problems. In the analysis of patient satisfaction with the clinic consultations, there was a statistically significant difference between the two modes of care, in favour of the nurse practitioner, in the areas of communication and time spent with the patient. However, nurse practitioner-led care resulted in significantly increased resource use compared with doctor-led care. The mean difference per patient was £1498 (95% CI, 688 to 2674; $p < 0.001$) and was greater in the first year (£2625) than in the second (£411).

Conclusions

Nurse practitioner-led care for stable patients within a chronic chest disease clinic is safe and as effective as doctor-led care.

There was significant additional patient satisfaction with some aspects of nurse practitioner-led care and better patient compliance with antibiotic therapy.

There was significant additional resource use related to admissions and antibiotic prescriptions during nurse practitioner-led care. However, this may have been a learning curve effect, as the difference was substantially greater in the first year.

While the treatment and management of the study patients are broadly generalisable to other chronic disease clinics, the authors would not recommend extrapolation of results to acute onset diseases or diseases in which presentation and/or complications are wide-ranging or rapidly changing.

The study design – a randomised, controlled, crossover trial based on equivalence in outcome – proved robust and appropriate for this type of evaluation. Randomisation allowed the most objective treatment assignment over the period of study and ensured that unpredicted differences in hospitalisation and cost were detected; an alternative strategy could have masked these differences.

Recommendations for research

Similar evaluations should be considered as part of the process of introducing nurse practitioner roles, or any role transfer in the health service, as much can be learned from the results in terms of ensuring that their introduction is both acceptable to patients and cost-effective.

To minimise the learning curve effect in future studies of this type, randomisation during training and a formal evaluation of all outcomes immediately after training would help to identify needs and to minimise the learning curve effect during a period of formal evaluation. An alternative approach would be simply to lengthen the trial.

Chapter 1
Background

Management of bronchiectasis accounts for one in every 200 hospital admissions in England,[1] and the disease causes approximately the same number of deaths annually as multiple sclerosis in England and Wales.[2] Despite this level of morbidity and mortality, there has been little concerted effort to optimise management of such patients. Bronchiectasis is a chronic, usually progressive respiratory disease characterised by dilatation and thickening of the bronchi. Patients experience repeated episodes of infection, chronic sputum production and increasing breathlessness, which ultimately progress to respiratory failure. In the late stages of the disease, double lung or heart–lung transplantation are the only therapeutic options that will improve patients' quality of life and survival.

The lung defence clinic was introduced as a specialist unit at Papworth Hospital in 1995, with the purpose of streamlining the management of patients with bronchiectasis. At initial referral, patients are seen by the medical team and are investigated for causal factors for and precipitants of bronchiectasis. Individual management plans are developed for intensive treatment and prophylaxis of endobronchial sepsis. After initial investigation, patients with minor disease are followed-up at their local hospitals, returning to the tertiary centre for an annual review. Patients with moderate-to-severe disease are seen at the lung defence clinic approximately four times per year. It was in this context that the possibility of expanding the nurse practitioner role to include outpatient follow-up of chronic respiratory patients was considered as a potentially cost-effective and acceptable method of delivering care.

Early studies of nurse practitioner roles indicated that their care may be equivalent to that provided by physicians in some circumstances.[3–7] However, many studies were flawed owing to lack of appropriate control groups, small sample sizes, lack of randomisation, failure to account for differences in severity of illness and failure to measure outcomes.[8] In addition, concerns have been expressed about the generalisability of American studies to the UK situation.[9] Little has been published in relation to the nurse practitioner role in a UK setting. In its standard for education and practice following registration, *The future of professional practice*, the UK Central Council for Nursing, Midwifery and Health Visiting (UKCC) states that advanced nursing practice is '... concerned with adjusting the boundaries for the development of future practice, pioneering and developing new roles responsive to changing needs, and with advancing clinical practice, research and education to enrich professional practice as a whole'.[10] Several key criteria for recognition as an advanced nurse practitioner have been proposed, including being: an autonomous practitioner; experienced and knowledgeable; a researcher and evaluator of care; an expert in health and nursing assessment; an expert in case management; a consultant education leader, and respected and recognised by others in the profession. Nurses with experience and specialist training in respiratory medicine, educated to the level required to fulfil these key criteria, should be able to provide high-quality care to patients with chronic respiratory disease. In addition, the widely recognised expertise of nursing staff in communication, education and achieving patient compliance could greatly enhance the care that these patients receive.

With junior doctors working shorter hours, partly because of the EU working time directive, and the advent of specialist registrars, there is a pressing need to consider the most appropriate and effective way of managing patients with chronic chest diseases attending outpatient clinics.

If patients requiring routine monitoring and minor modifications to therapy could be managed by appropriately trained nurse practitioners, additional benefits might include continuity of care for the patients and freeing-up of senior medical time. Consultants could spend more time increasing the throughput of new patients, thus reducing waiting times and ensuring that care was optimised and treatments reassessed.

In many clinics, the primary motivation for introducing nurse practitioner care is to help existing medical staff cope with increasing patient workload. Furthermore, nurse practitioner-led care is often viewed as a cheaper, more cost-effective alternative to doctor-led care, which might be a

secondary consideration in any decision to employ a nurse practitioner. However, in the short term, the introduction of nurse practitioner-led care is unlikely to save NHS resources. The costs of employing, training and supervising the nurse practitioner will tend to outweigh any initial savings. The nurse practitioner may reduce the clinical burden on the rest of the medical team but, in most clinics, new patients from the waiting list would quickly fill this spare capacity, which would lead to additional investigation and prescription costs. Despite this, over a longer period, nurse practitioner-led care can conserve resources by reducing the need to employ extra consultant physicians or specialist registrars to deal with increasing patient numbers.

The successful inclusion of a nurse practitioner in a care team could thus have several quality benefits for this group of patients in terms of access to and quality of care. Potentially, there could be other wider benefits for the NHS in the development of the nurse practitioner role and its evaluation in the context of a randomised controlled trial (RCT).

- If the trial showed that nurse practitioner-led care was clinically safe, and cost-effective and acceptable, it might be applied to other similar patient groups and other clinics, such as those held in district general hospitals.
- The training module developed during the study could be of value in training future nurse practitioners.
- The methodology employed, using a crossover trial design, could if successful inform future studies aimed at evaluating extended roles for nursing staff.
- The prospective, systematic collection of clinical and health-related quality-of-life data for patients with bronchiectasis would be extremely valuable in providing comparisons with other groups with chronic respiratory disease, in particular, patients with asthma, chronic obstructive pulmonary disease and cystic fibrosis.

Chapter 2

Study design

Aim

The aim of the trial was to test the hypothesis that patient function was not affected by nurse practitioner-led care, using forced expiratory volume in 1 second (FEV_1) as the primary outcome measure. The study was designed to assess the feasibility and safety of nurse practitioner-led outpatient clinics, to test the acceptability of such clinics to patients and their doctors, and to compare the costs of nurse- and doctor-led systems of care.

Study phases

The study was in two phases: training the nurse practitioner and the RCT.

Phase 1 – training the nurse practitioner

Appropriate nurse practitioner training was considered central to the safety of practice and the outcome of this study. In order to practise independently, the nurse practitioner needed to acquire a detailed theoretical knowledge of bronchiectasis and its management, together with practical experience and skills in clinical assessment and therapeutics. A 9-month training programme was devised, with a core curriculum that involved:

- tutorials on the theory of the principles of disease and its clinical presentation, the underlying causes, associated pulmonary disorders, pulmonary function and microbiology
- a radiation protection course to enable the nurse practitioner to order X-rays
- in-hospital training in pharmacology and therapeutics, aimed at enabling the prescribing of drugs, blood tests and pulmonary function tests, in accordance with the patient's treatment plan
- nurse practitioner attendance at clinics, post-clinic patient reviews and ward rounds, with detailed discussion of changes in practice with the attending consultant and the patient.

Further details of the training programme are given in appendix 1.

Phase 2 – the RCT

The study was a two-period, two-treatment, crossover trial, with patients receiving two 1-year blocks of care led by either a nurse practitioner or medical staff. The order in which these blocks were assigned was randomised. It was crucial that patients received each method of care for a full year, because chronic lung disease is subject to seasonal variation. Three consultants and one rotating registrar with 2–3 years experience of respiratory medicine made up the medical staff team. Randomisation was stratified by the patients' respiratory function, defined as stable (decline in FEV_1 over the preceding 12 months of more than 5%) or unstable (decline in FEV_1 in the preceding 12 months of up to 5%), prior to randomisation. Contrary to expectations, there were very few unstable patients and, hence, analysis of this subgroup was not considered appropriate as it would not provide any important additional information.

As the aim was to establish the equivalence of nurse practitioner care, it was important to choose a study design that was very sensitive to small changes. Another consideration that led to the choice of a crossover rather than a simple parallel group design was that it was judged to be more acceptable to patients and general practitioners (GPs), thus minimising potential difficulties in the recruitment of patients. In addition, because of the large between-patient variation compared with within-patient variation, a parallel randomised trial would have required a much larger sample. Carryover effects were considered negligible in this context, so that no 'washout' period was used.

Study population

Inclusion criteria

- Patients over 18 years of age who attended the lung defence clinic at Papworth Hospital, with moderate or severe bronchiectasis confirmed by high-resolution computed tomography (CT) scan.
- A treatment plan was formulated before a patient was considered eligible for the trial. The nurse practitioner did not assess new patients independently.

Exclusion criteria

- Life expectancy of less than 2 years.
- An expected need for transplantation listing within 2 years.
- An FEV_1 value that was less than 30% of that predicted.
- Any other significant pathology that would modify the management of bronchiectasis.

Sample size

Sample size was calculated on the basis of establishing equivalence between nurse practitioner- and doctor-led care. In practice, the aim was to exclude a difference of at least 5% predicted FEV_1 between the two methods of care delivery. Assumptions were a standard deviation (SD) of 12.5%, at least 80% power, a two-tailed α value of 5%, and a patient drop-out rate from the study of 10–15%. Using standard methods,[11] the required sample size was was calculated to be 80 patients.

Recruitment

During the nurse practitioner training period, 149 patients were identified from the lung defence clinic. Of these, 40 patients were unsuitable for inclusion in the trial because of: relocation to another area (4); minimal or mild bronchiectasis cared for by the patient's local hospital (13); no management plan in place during the recruitment period (6); $FEV_1 < 30\%$ (7); age < 18 years (1); other medical conditions requiring more complex management (9). Of the 109 patients eligible for recruitment, seven refused or did not reply to recruitment letters; hence, of the remaining 102 patients, the first 80 to attend the clinic were recruited (*Figure 1*). The Huntingdon Research Ethics Committee approved the study, and all patients gave written informed consent to their inclusion in the study.

Randomisation

Randomisation was organised in the hospital's Research & Development Unit and was supervised

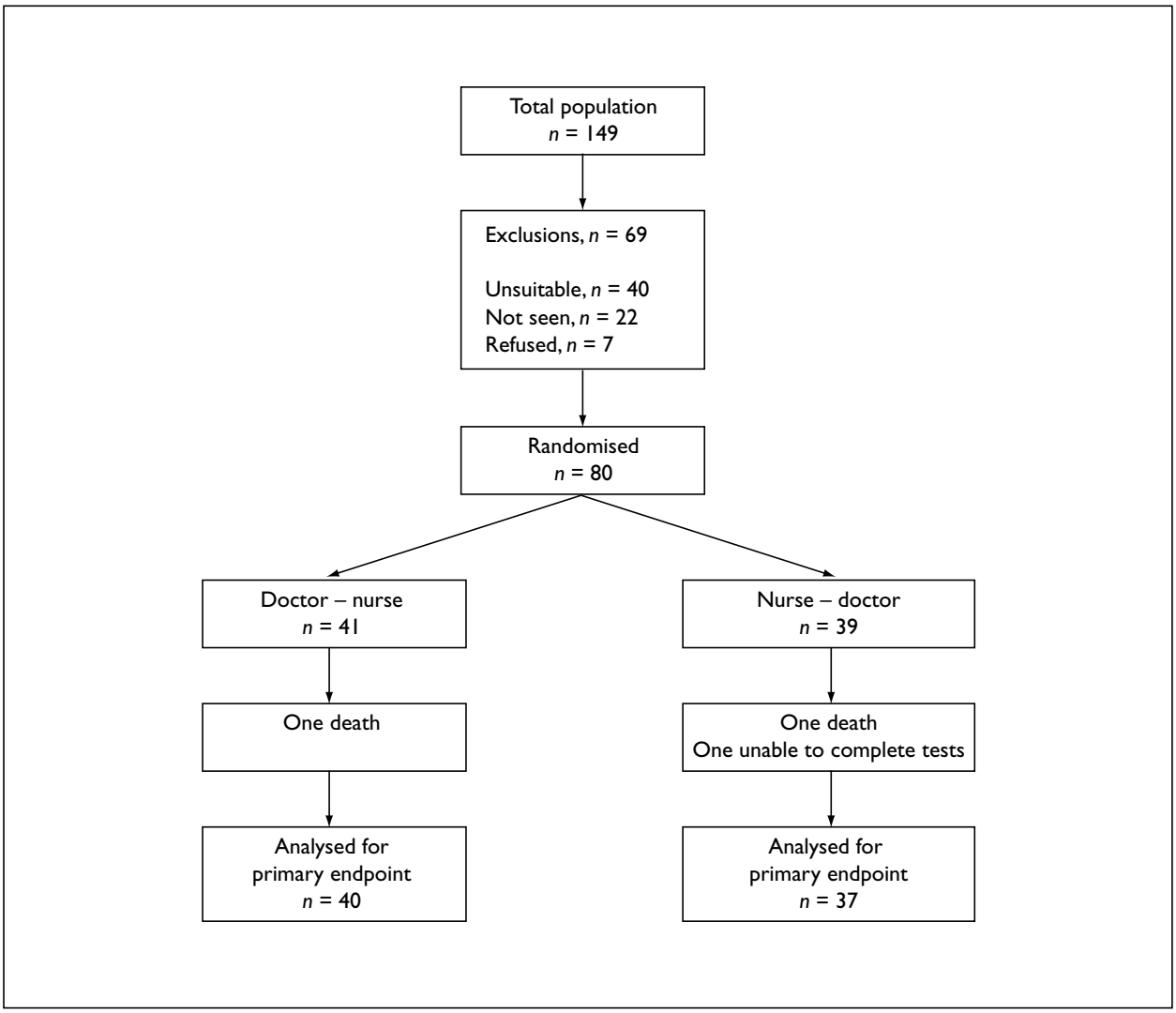

FIGURE 1 *Flow chart of patients considered for the trial*

by the project statistician independently of the investigators who had direct patient contact. The consultant handling the consent procedure for the patients was issued with a series of numbered, opaque envelopes, containing a registration form and the order of care for the patient. The registration forms served as an independent recruitment check. Randomisation was of a random permuted block design, with block lengths of four and six to ensure a roughly constant case load throughout.

Intervention

On arrival at the clinic, patients received routine tests, followed by a consultation with the nurse practitioner or a doctor that involved a clinical assessment of their lung disease, including history and examination, followed by a discussion of the treatment management plan. Changes were made to treatment and care, and further tests, such as X-rays and blood tests, were ordered as appropriate. Follow-up appointments were organised at the discretion of the nurse practitioner or doctor; these were weekly for patients on intensive intravenous antibiotic therapy at home, every 2 weeks to assess the results of a course of antibiotics, and every 3–6 months for routine monitoring of the patient's disease. At randomisation, patients were given the name and telephone number of the appropriate contact, that is, either nurse practitioner or doctor, and encouraged to ring if they had any queries about their disease and its management. If a patient made contact, the nurse practitioner had the same authority as the doctor to decide whether a patient should be seen sooner than planned at clinic, or to advise the patient to see their GP or to take their reserve antibiotics. If a patient presented with a general, systemic problem that was not covered by the bronchiectasis disease management guidelines or if he/she needed to be admitted to hospital, the nurse practitioner was required to refer such issues to a consultant.

Patient safety

Strict supervision of the nurse practitioner was built into the study design. A doctor was available for advice if required and supervision sessions were held within 24 hours of the clinic. These involved a detailed discussion of the patient's condition and management (see appendix 2). If the consultant would have taken a different course of action, the patient was informed immediately and arrangements made to amend his/her management.

An interim cross-sectional analysis was performed after the first year of the trial to ensure that the introduction of the nurse practitioner had not led to a clinically significant deterioration in care.

Outcome measures

The primary measure of the effect of nurse practitioner-led care was the difference between FEV_1 measurements at the end of each year of treatment (see chapter 3).

Secondary outcome measures were:
- forced vital capacity (FVC) and a 12-minute walk (chapter 3)
- the number of infective exacerbations requiring intravenous antibiotics (chapter 3)
- the number of admissions to hospital (chapter 3)
- nurse practitioner autonomy (chapter 3)
- health-related quality of life (chapter 3)
- patient and GP satisfaction with care (chapter 3)
- patient compliance with care (chapter 3)
- resource use (chapter 4).

The measures of disease and lung function were recorded by technicians who were independent of the trial. In the schedule of events presented in *Box 1*, the types of outcome measurement are outlined, together with the measurement intervals during the trial.

Statistical analysis

All patients who failed to complete the trial period were documented. Patients who failed to cross over to nurse practitioner-led care were included in the trial on an intention-to-treat basis. Although intention-to-treat is conservative and generally not recommended for an equivalence trial, exclusion of these patients may introduce important bias. A secondary analysis of the primary outcome was undertaken in which these patients were excluded and the treatment effects were found to be almost identical (these results are not presented here).

The approach to analysis followed that of Hills and Armitage,[12] using paired student *t*-tests to assess the significance of the effect of mode of care (nurse practitioner-led compared with doctor-led care) and period (first year compared with second year of the trial). Changes between the two periods were tested but no important period effects were observed; hence, these are not reported further. No carryover was assumed.

Means and 95% confidence intervals (CIs) for FEV_1 were calculated, along with effects of mode of

BOX 1 Schedule of events

Outcome measure	Performed at				Performed at	
	Recruitment	6 months	12 months		18 months	24 months
Tests						
Pulmonary function tests	X	X	X	C	X	X
12-minute walk	X		X	R		X
Sputum production	X		X	O		X
Sputum bacteriology	X		X	S		X
Interviews				S		
Health-related quality of life	X	X	X	O	X	X
Patient compliance			X	V		X
Patient satisfaction			X	E		X
GP questionnaire			X	R		X
Resource use diary		X	X		X	X

care. The effect of time was expected to be negligible in this case but was assessed for completeness. Similar methods were used to assess changes in health-related quality-of-life scores. Infective exacerbations and admissions to hospital were expressed as the number per patient year of follow-up. These measurements were assumed to follow a Poisson distribution and modes of care were compared using a likelihood ratio test.

The results of the patient satisfaction questionnaire were evaluated in two ways. First, each question was scored from 1 (least favourable response) to 3 (most favourable response). The scores for the 12 questions that dealt with the consultation (questions 5–16) were then summed, to give an overall level of satisfaction score of between 12 and 36. The scores for each patient recorded in each mode of care were compared using the Wilcoxon signed ranks test. Second, each question was categorised as 1 (most favourable response) or 0 (less than most favourable response), and the responses were compared between methods of care using the McNemar test. No adjustments for multiple testing were made, so these results should be interpreted with caution.

During the design stage of this study, there were no published data available to inform power estimates for the cost analysis. However, bronchiectasis is a chronic condition that occasionally requires expensive antibiotic therapy and hospital admission. This, coupled with the high inherent variability in healthcare costs, indicates that this study had limited power to detect small differences in cost between the two forms of care.

Cost data tend to be heavily positively skewed. Under such circumstances, the use of the student *t*-test to compare differences in means may be invalid, particularly with small sample sizes.[13] Hence, a paired non-parametric bootstrap analysis was used[14] to derive a 95% CI around the mean difference in cost between nurse practitioner-led and doctor-led outpatient care.

Chapter 3

Clinical and patient outcomes

Study compliance

Two patients died just after the 12-month follow-up, one from a perforated bowel in the nurse practitioner-led care group and one from end-stage respiratory failure in the doctor-led group. One patient did not undergo any pulmonary function or exercise tests at the 2-year visit because of a fractured rib unrelated to bronchiectasis. These patients were excluded from the analysis of the primary outcome, FEV_1. In addition, two patients were unable to complete the 12-minute walk test: one had a fractured toe (at 12 months) and another was too sick (at 24 months) – both received doctor-led care in the year before. Otherwise, all patients completed the clinical outcomes. Two different patients refused to complete quality-of-life interviews, one at 12 and one at 24 months, both at the end of nurse practitioner-led care. Six patients who received doctor-led care in the first 12 months required revised management plans during that time, thus preventing their crossover to nurse practitioner-led care.

Baseline measurements

Of the 80 patients recruited, 39 were randomised to nurse practitioner-led care followed by doctor-led care and 41 to doctor-led followed by nurse practitioner-led care. The average age at randomisation was 58.3 years (SD 13.3) and 55 (69%) of the patients were women. These characteristics were similar to those of patients who were not recruited to the study. Baseline lung functions and 12-minute walk distances were similar for both groups (*Table 1*).

Clinical outcomes

The clinical measures observed at the end of each treatment period are shown in *Table 2*. The mean difference in FEV_1 between nurse-led and doctor-led care was 0.01 litres (95% CI, –0.04 to 0.06), $p = 0.79$, or 0.2% predicted (95% CI, –1.6 to 2.0), $p = 0.83$. In addition, there was no change in FVC between the two treatment periods (mean difference –0.02% (95% CI, –1.5 to 1.4), $p = 0.84$). The mean difference in 12-minute walk distance between the two methods of service delivery was 18 metres (95% CI, –13 to 48), $p = 0.30$. This analysis was repeated excluding those patients who failed to crossover to nurse practitioner-led care, with very little change in size or precision of results.

The number of infective exacerbations experienced by patients during nurse practitioner-led care was 262 in 79.4 patient-years of follow-up, compared with 238 in 77.8 years during doctor-led care. Thus, nurse practitioner-led care resulted in a relative rate of exacerbations of 1.09 (95% CI, 0.91 to 1.30), $p = 0.34$.

During doctor-led care, there were 42 admissions to hospital compared with 66 during nurse practitioner-led care, a relative rate of 1.52 (95% CI, 1.03 to 2.23), $p = 0.03$. Of these, 23 and 43 readmissions were related to the patients' bronchiectasis, a relative rate of 1.59 (95% CI, 0.75 to 3.39), $p = 0.22$.

TABLE 1 *Baseline measures of pulmonary function and exercise capacity: mean and SD*

Order of care	Nurse-led/doctor-led *n* = 39	Doctor-led/nurse-led *n* = 41
Age, (years)	63.7 (10.3)	53.1 (13.8)
Female, *n* (%)	26 (67)	29 (71)
FEV_1 (%)	70.4 (23.4)	70.3 (17.5)
FVC (%)	87.0 (18.6)	85.5 (16.6)
12-minute walk distance (metres)	712 (175)	758 (204)

TABLE 2 *Main clinical measures during nurse practitioner-led and doctor-led care: mean and SD*

	Nurse-led care	Doctor-led care	Mean difference Nurse – Doctor (95% CI)
FEV_1 (litres)	1.87 (0.78)	1.86 (0.81)	0.01 (–0.04 to 0.06)
FEV_1 (%)	69.7 (20.8)	69.5 (21.7)	0.2 (–1.6 to 2.0)
FVC (%)	87.6 (19.3)	87.6 (19.4)	–0.02 (–1.5 to 1.4)
12-minute walk distance (metres)	765 (188)	746 (197)	18 (–13 to 48)

Nurse practitioner autonomy

While patients were being managed by the nurse practitioner, all incidences of medical staff being required to give advice or alter management supervision were documented. These data were used to measure the degree of nurse practitioner autonomy, to monitor any adverse events and to highlight any training needs.

During the trial period, the nurse practitioner completed 436 patient consultations. There were three occasions when the consultant requested further action. Patient one was prescribed antibiotics by the nurse practitioner but the consultant was keen to redefine the patient's specific antibody deficiency. At the consultation, the nurse practitioner had discussed further investigations but the patient felt well and was reluctant to undergo further tests. Further investigations are ongoing. The impact of this was considered minor. Patient two was well and planning a trans-Atlantic holiday. The nurse practitioner did not order blood gas tests in order to identify any need for oxygen therapy during the flight. The impact of this was considered moderate, as the patient was contacted and returned for blood gas assessment. Patient three had diverticulitis that was not being addressed. The nurse practitioner brought it to the attention of the consultant at the post-clinic meeting at which further action was planned. In this case, the nurse practitioner behaved entirely appropriately as further action outside her specialist area was required.

Health-related quality of life

Patients completed a general health status questionnaire, the Short Form 36 (SF-36) Health Survey,[15] and two disease-specific measures, the Chronic Respiratory Index questionnaire (CRIQ)[16] and the St George's Hospital Respiratory questionnaire.[17] Copies of these questionnaires are presented in appendix 3.

In the original development studies of the SF-36 in the USA, it was possible to distinguish between chronic respiratory disease patients and the general population on the scales from which the health survey was derived.[18] In a study of 200 patients with chronic obstructive pulmonary disease, the SF-36 correlated well with tests of respiratory function.[19] The SF-36 has eight dimensions: physical functioning, role limited due to physical problems, role limited due to emotional problems, social functioning, mental health, energy/vitality, pain, and general health status. Dimensions are scored from zero to 100, with 100 representing maximum health status.

The CRIQ is used to measure dyspnoea, fatigue, emotional function and mastery of disease, and is regarded as the most comprehensive disease-specific measure for respiratory conditions. It has been proved to be capable of detecting the slight changes in condition that might prove to be important in this study.[16] The CRIQ dimensions are 24–42-point scales, with high scores representing maximum health status.

The St George's Hospital Respiratory Questionnaire,[17] which has been validated in bronchiectasis patients, measures levels of symptomatology, physical activity, and impact of the disease on daily life. Scores range from zero to 100, with zero representing maximum health status, and the three dimensions can be combined into an overall score.[20]

All the questionnaires were administered by a research assistant who was not involved in the care of the patients. An attempt was made to mask the research assistant to the patient group. However, checks made after all patients had completed 12 months of care suggested that the masking attempt had failed.

The mean SF-36 scores with 95% CIs, at baseline and at 12 and 24 months, are shown in *Figure 2*. Overall, the patients' scores at 24 months were either equivalent to or slightly higher than those

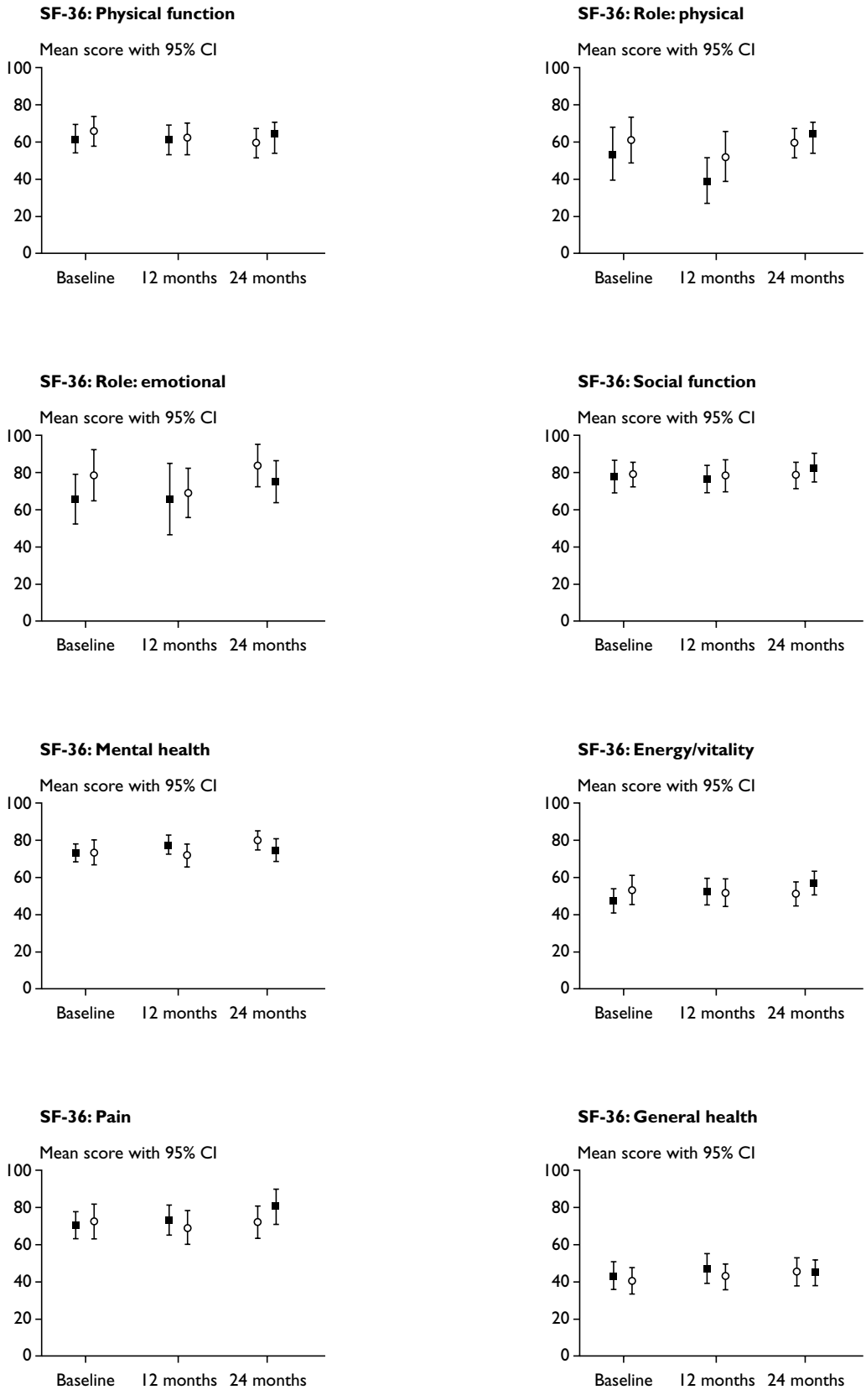

FIGURE 2 *SF-36 mean scores and 96% CIs for patients at baseline and at 12 and 24 months (■, nurse; ○, doctor)*

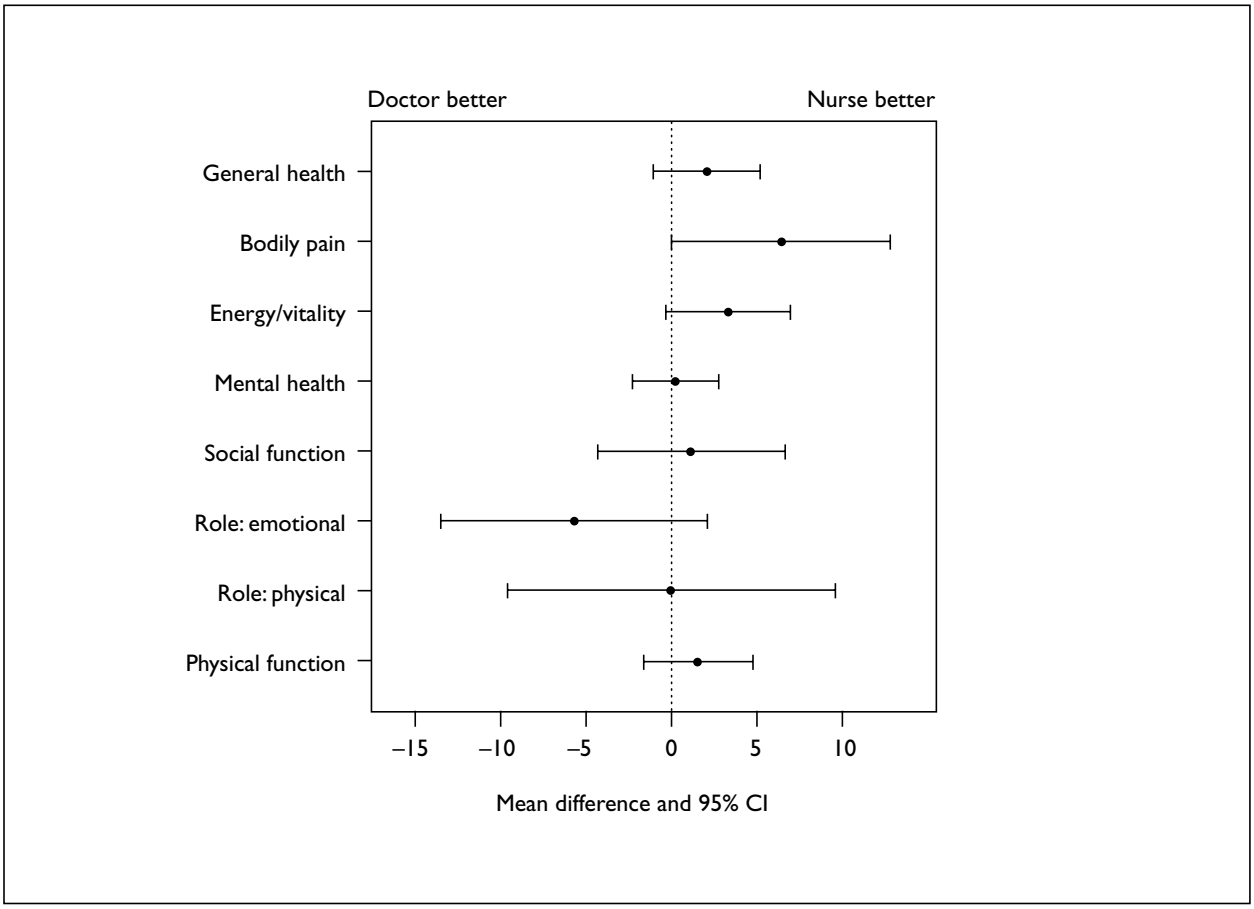

FIGURE 3 *Mean differences and 95% CIs for SF-36 profile scores between nurse practitioner-led and doctor-led care*

at baseline. In the physical dimensions, the scores were mostly in the range 50–80 points on the 0–100 scale over the 2-year period; the lowest scores were in general health, 42–45, whereas the least affected aspect of quality of life appeared to be social functioning, with a score of 78. In *Figure 3,* differences in SF-36 dimensions between nurse practitioner-led and doctor-led care are plotted (mean difference with 95% CIs, and zero indicating equivalence). In comparing the two modes of care, patients reported fewer role limitations owing to emotional problems following doctor-led care and more vitality/energy and lower levels of pain following nurse practitioner-led care, although the differences were not significant.

The disease-specific questionnaire mean scores with 95% CIs are shown in *Figure 4*. In the CRIQ, there was some decline in the dyspnoea score (indicating deterioration) for the whole group over time. In comparing the two modes of service delivery (see *Figure 5*), patients reported fewer symptoms and less impact of their disease on daily life following nurse practitioner-led care but there were no clinically or statistically significant differences between the two modes of care.

Compliance and satisfaction with treatment

In order to assess any changes in patient compliance with treatment during the course of the trial, and equivalence between the two modes of care, patients were asked to complete questionnaires at 12 and 24 months; these asked about frequency and compliance with physiotherapy, use of inhalers and antibiotic therapy (see appendix 4). Of the 80 patients participating, 64 completed the questionnaire following nurse practitioner-led care and 66 following doctor-led care. The results indicated that:

- more than 90% of patients (122/130) were receiving physiotherapy once or twice daily and, of these, about 60% stated that they had missed less than 1 or 2 days of physiotherapy over a 6-month period
- the main reason for missing physiotherapy was that it interfered with routine/life/commitments
- of the 62% of patients (81/130) who had been prescribed preventer inhalers, the vast majority (95%) had been asked to use them twice a day and compliance was very high

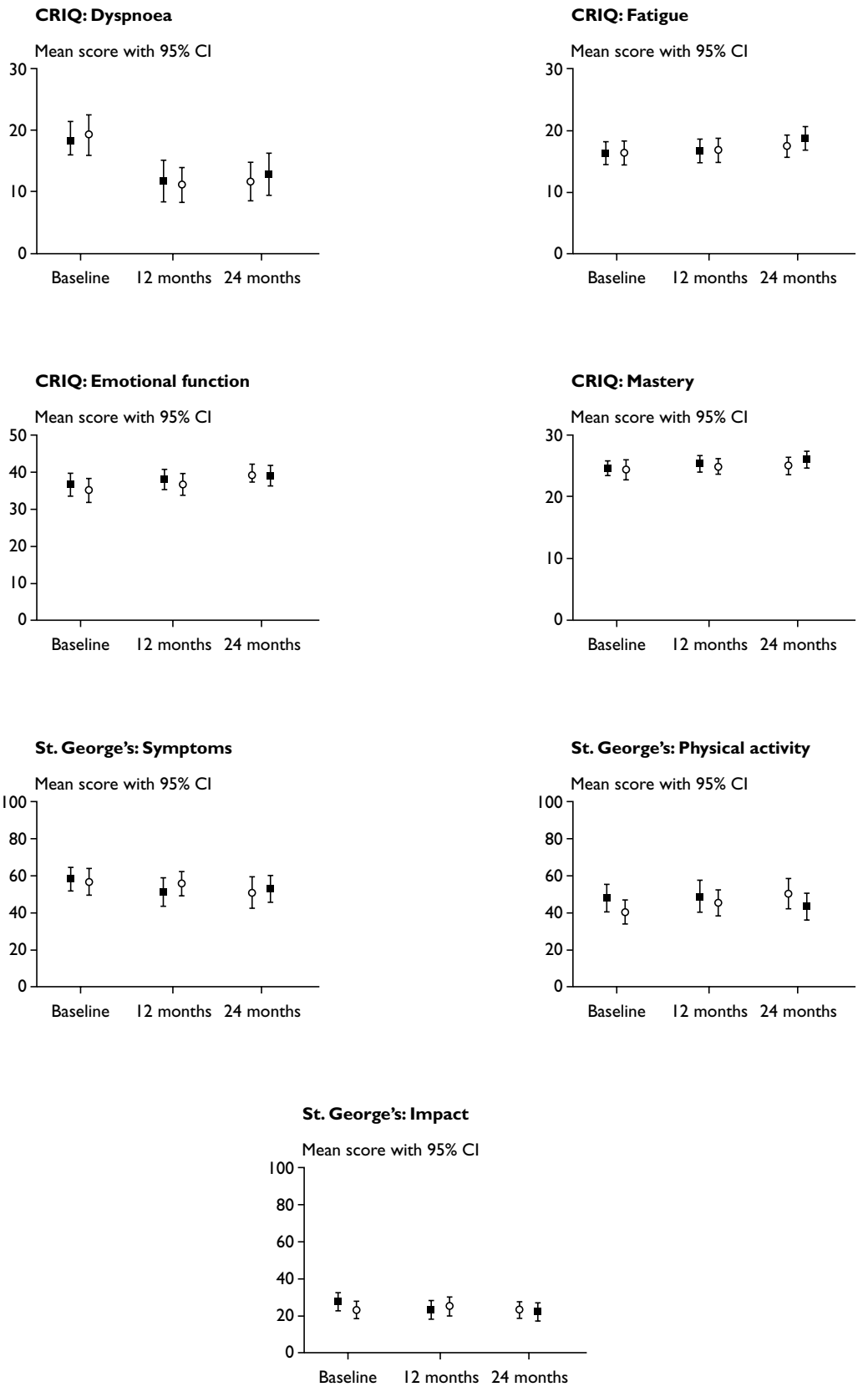

FIGURE 4 *Mean scores and 95% CIs from the CRIQ and St. George's Hospital Respiratory Questionnaire (St. George's) at baseline and at 12 and 24 months (■, nurse; ○, doctor)*

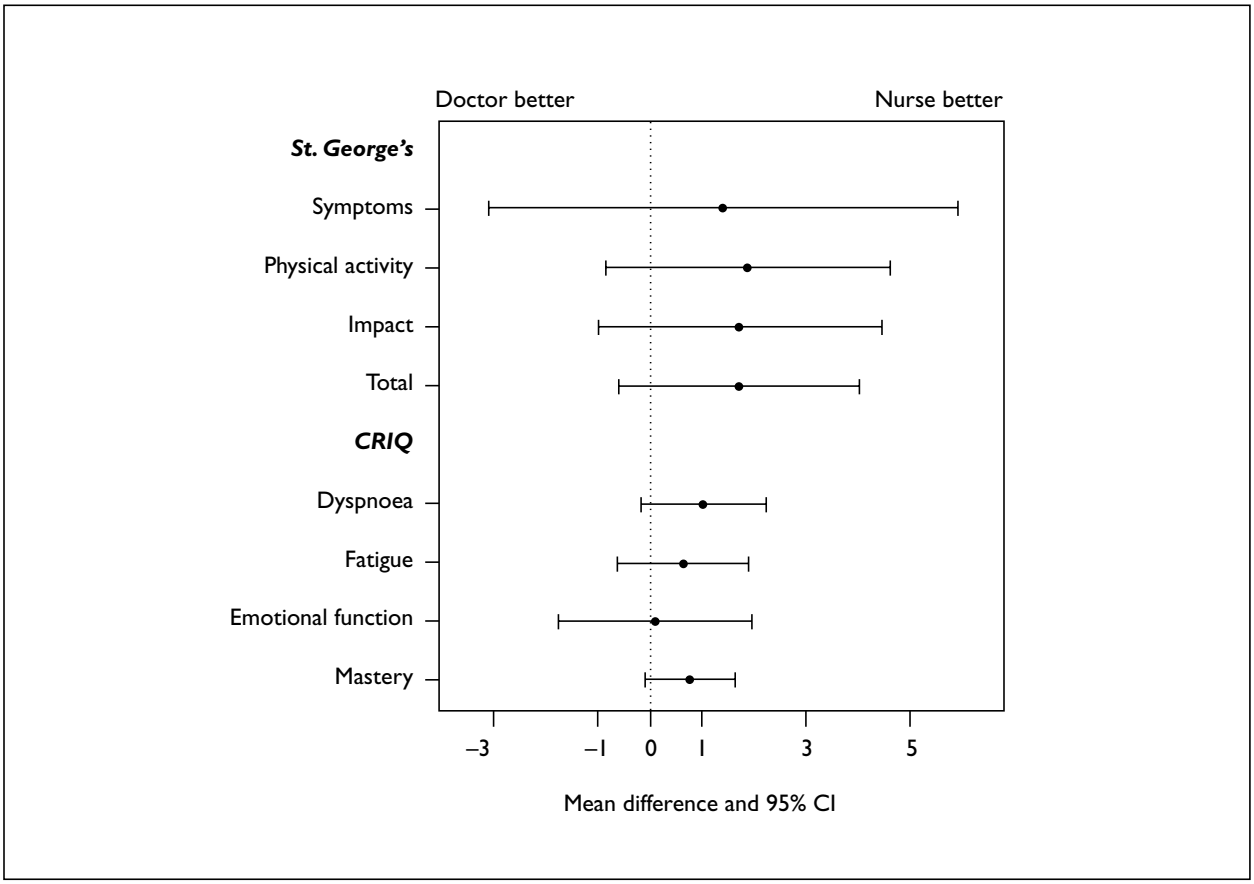

FIGURE 5 *Mean differences and 95% CIs for disease-specific health-related quality-of-life scores between nurse practitioner-led and doctor-led care (St. George's = St. George's Hospital Respiratory Questionnaire)*

- about half of the patients (61/130) were using antibiotics and, again, compliance was high
- of the 31 patients who were using antibiotics and indicated their compliance while receiving nurse practitioner-led care, 100% were compliant (95% CI, 89 to 100), compared with 81% (95% CI, 63 to 93) of the 31 patients in doctor-led care; this difference was statistically significant ($p = 0.024$).

Patients' satisfaction with the care they received, and GPs' satisfaction with communications about care and quality of care given to their patients, were assessed by questionnaires and anonymous patient reports. Copies of these questionnaires are presented in appendix 5.

The patient questionnaire was devised from one used previously in a specialist outpatients' clinic. The domains covered were the organisation of the clinic and the quality of the consultation with the doctor or nurse practitioner. The particular aim was to explore aspects pertaining to the quality of communications between the clinician and the patient, satisfaction with the time spent in the consultation, and confidence in the clinician's understanding of the patient's history. The questionnaire was structured using 16 statements to which patients were asked to agree or disagree, using a three-point Likert-type scale. The first four questions were concerned with the clinic environment and car parking, and the remaining 12 related to the consultation. In addition, the patients were asked what they liked most and least about the care they received at the clinic, and if they had any suggestions for improvements. The questionnaires were administered to patients by the research assistant who was not involved in delivering patient care.

In analysing the individual 12 statements relating to the doctor/nurse consultation, there were statistically significant differences between the two modes of care, in favour of the nurse practitioner (*Table 3*), although the levels of significance should be treated with caution owing to the multiple testing involved. However, the direction of differences in favour of the nurse practitioner was consistent, and the aspects of care – related to communications and spending more time with patients – were also consistent with what would be expected to be strengths of the nurse practitioner.

TABLE 3 *Patient satisfaction with consultation: number (%) of patients recording most favourable response*

Comments	Nurse practitioner better	Doctor better	*p*-value
	Number (%)	Number (%)	
It was sometimes difficult to discuss your problems with the doctor/nurse practitioner	11/76 (14.5)	1/76 (1.3)	0.006
The doctor/nurse practitioner explained clearly what is wrong	7/74 (9.5)	0/74 (0.0)	0.016
The doctor/nurse practitioner examined you thoroughly when necessary	6/70 (8.6)	0/70 (0.0)	0.031
The doctor/nurse practitioner should tell you more about your illness/condition and treatment	7/59 (11.9)	3/59 (5.1)	0.344
The doctor/nurse practitioner made you feel at ease	2/75 (2.7)	1/75 (1.3)	1.000
There was not enough time to discuss your problems with the doctor/nurse practitioner	10/74 (13.5)	1/74 (1.4)	0.012
You felt confident the doctor/nurse practitioner knew about your medical history and your care	7/74 (9.5)	1/74 (1.4)	0.070
Sometimes you felt that the doctor/nurse practitioner should listen more to what you said	5/69 (7.2)	2/69 (2.9)	0.453
The doctor/nurse practitioner gave a clear explanation about any tests that you needed	4/75 (5.3)	1/75 (1.3)	0.375
You often came away from your appointment wishing you'd asked more questions	13/72 (18.1)	9/72 (12.5)	0.523
You felt you were given a chance to have an active part when discussing your illness/condition	4/73 (5.5)	0/73 (0.0)	0.125
There were frequent interruptions during your consultation	6/73 (8.2)	3/73 (4.1)	0.508

There were equal numbers of comments from patients completing a year of nurse practitioner-led and a year of doctor-led care. Many comments highlighted the patients' confidence in the system and their appreciation of the holistic approach to care. Those aspects of the experience that patients liked least and considered could be improved were related mainly to car parking, waiting times at the clinic and the waiting area. These same issues were raised at follow-up intervals. There were also nine negative comments about the questionnaires being used in the trial, three at 12 months and six at 24 months.

All comments specific to aspects of continuity of care and communications, positive and negative, together with a selection of the many positive comments on staff attitudes and satisfaction with care, are included in *Boxes 2* and *3*.

GPs were sent postal questionnaires, at 12 and 24 months, asking them how many times they had seen their patient during the last 12 months and how many of these attendances were due to the patient's bronchiectasis (appendix 5). If a GP needed advice from the clinic, they were asked to rate ease of communication, advice and information received by letter, and the care their patient received, on a four-point scale ranging from very poor to very good.

There was no difference in the frequency of visits to GPs, for bronchiectasis or other reasons, during nurse practitioner-led and doctor-led care. There were only 16 instances of GPs seeking advice from the specialist clinic team during the period of the trial. On nine occasions, this was for patients being cared for by the nurse practitioner and on seven for patients receiving care from a doctor. In all cases, the GPs rated ease of communication, the quality of advice given and the care received by the patients as either 'very good' or 'good', with the exception of one rating of 'poor' for ease of communication during nurse practitioner-led care.

BOX 2 Comments during nurse practitioner-led care

Continuity

"Good to see the same person – more continuity, making it unnecessary to cover the same ground. Friendly/personal – not just another body."

"One department. Everyone is friendly and [I] feel relaxed and welcome. Care doesn't stop when the clinic is not open. Nurse practitioner is always contactable and will answer queries. I feel more confident about my health and the future after being transferred to Papworth."

"... it is also very reassuring that if I am unwell in between appointments, I have been able to ring the nurse practitioner to discuss this."

Communication

"Nurse practitioner most supportive and has taken trouble to listen and be helpful. Felt she is knowledgeable in her area of expertise."

"... time given, friendliness; condition understood and treated professionally. Able to discuss worries. I know I can contact someone if I need to."

"Able to put forward own thoughts and feelings about chest problems and discuss them. I am very pleased that I have not been forced to take steroid tablets."

"The way everything has been explained."

"Everyone is efficient, take time to explain clearly what is happening; everyone is friendly."

"Nurse practitioner very helpful and clear with instructions and concerns."

"Everything is explained fully and it's a relaxing, pleasant appointment."

Staff attitude and satisfaction with care

"... friendliness and efficiency of the staff. I have confidence [in them]."

"Care and understanding of all the staff and doctors, I feel, is second to none."

"You don't feel like a patient, more like a friend. Everyone is friendly and helpful."

"The care I received was excellent at all times."

BOX 3 Comments during doctor-led care

Continuity

"The best appointments were with the nurse practitioner – seeing the same person every time helped enormously and there always seemed to be enough time to discuss everything and think things through; interviews were very thorough."

"... do not see same doctor. The relationship I have built [with one consultant] allows me to speak frankly and she knows my condition and me as a person. I have seen [another consultant and a registrar] and, although I'm sure they have read my notes, it's not quite the same. With an ongoing condition, continuity of care is most important."

"Continuity by the nurse practitioner was superb. I think it really helps if you can see the same person on a regular basis, and I know backup is there from her if a problem arises."

"I feel that my condition is understood and that the staff work closely as a team to do what is possible to manage it. I feel that if there is a crisis, I can have access to the best diagnostic skills available."

"... difficulty in not being able to speak to consultant or nurse between appointments while on consultant-led trial – always difficult to get hold of or too busy. I find it upsetting not being able to discuss your problems with nurse practitioner while on doctor's trial (with consultant)."

"... seeing the same person for consultation. I know cases are discussed with all medical staff present later that day but if I've been seen by someone new who doesn't know me, they may not pick up on something in the same way because I'm nervous and I may forget. It's not easy explaining yourself to someone different every time you come to clinic and I wouldn't expect them to wade through all the notes before seeing me, so it is difficult to get round this."

"... different doctors each time ... having to repeat basic questions about history at every visit."

Communication

"... willingness of staff to discuss and explain my illness and listen to any concerns that I may have. The specialist nurse inevitably has more time to talk and listen to patients."

"Everyone cares and is so helpful. I never feel worried about my condition because I know I can always contact the nurse practitioner should I have a problem and then it will be sorted. It is wonderful to be able to have such confidence in the system."

"... able to talk about the condition..."

Staff attitude and satisfaction with care

"Everyone is always very friendly and willing to help. A smiling face makes you feel confident about asking anything that may be bothering you."

"Staff remember your name from previous visit. Everyone is helpful and supportive and give you confidence that your condition is being monitored by caring experts."

"... treated as a person not an object – all staff are helpful – can talk out fears with doctors – very pleasant staff."

"I feel that my condition is understood and that the staff work closely as a team to do what is possible to manage it. I feel that, if the need arises, I can have access to the best diagnostic skills available."

Chapter 4

Economic evaluation

Type of economic evaluation

The primary economic evaluation was planned as a cost minimisation analysis from the perspective of the NHS. Briggs and O'Brien[21] recently highlighted the overuse of cost minimisation analyses; however, their comments were specifically aimed at comparative rather than equivalence trials.[11] In a comparative trial, designed to detect a difference between two treatments, lack of a **statistically** significant effect can easily be confused with the lack of a **clinically** significant effect. Thus, if a cost minimisation analysis is conducted solely on the basis of no statistically significant difference in outcomes, potentially important information about differences in effectiveness is being disregarded, thereby prejudicing the evaluation. However, this does not apply to the present study or to other equivalence trials. In this trial the aim was to exclude a difference of at least 5% of the predicted value of FEV_1 between the two methods of care – a difference that is considered clinically insignificant. Provided that equivalence is proven, cost minimisation analysis is appropriate. In the event that equivalence is not demonstrated, a cost-effectiveness acceptability curve would be used to demonstrate the joint distribution of incremental costs and effects.[14] The aim of the economic evaluation was to measure the long-run incremental costs of nurse practitioner-led care.

Resource use data collection

The main economic analysis was a comparison of the direct health service costs over 1 year of nurse practitioner-led and doctor-led care. The data collection methods are summarised in *Table 4*.

Resources used for outpatient visits, tests and procedures, drug prescriptions, hospital admissions and general practice visits were identified for every patient at 6-monthly intervals throughout the trial. At each outpatient visit, the clinician leading the clinic completed a consultation record form. This provided information on the date of the visit and any investigations and procedures ordered (see appendix 6). Patients recorded the length of each consultation; missing values were replaced by the average patient and provider specific consultation times. Details of microbiology and immunology tests were obtained from hospital databases, and procedures, investigations and intravenous antibiotics from patient records. Details of patient admissions to Papworth Hospital, including length of stay, were abstracted from the patient administration system. A patient diary card was used to collect information on drug utilisation (name, dose, frequency and duration), GP visits, and care received at other hospitals (see appendix 7). Patients were asked to complete the diary every time they visited their GP, changed their regular

TABLE 4 *Resource use data collection methods*

Resource type	Data source
Direct health service costs	
Nurse practitioner training	Nurse practitioner's record of time spent attending tutorials, clinics and ward rounds
Inpatient admissions and procedures:	
Papworth hospital	Papworth hospital patient administration system
Other hospitals	Patient diary
Number of outpatient visits	Consultation record form
Duration of outpatient visits	Recorded by patients
Tests and investigations	Consultation record form
Outpatient drug prescriptions	Medical record
Other drugs	Patient diary
Primary care visits	Patient diary
Non-health service costs	
Patient's time taken off usual activities	Patient diary

TABLE 5 *Cost of training the nurse practitioner*

Job description (trainer)	Grade[a]	Cost per hour (£)	Number of hours	Total cost (£)
Trainer				
Consultant immunologist		82[b]	17	1394
Consultant respiratory physician		82[b]	15	1230
Staff nurse	E	17[b]	3	51
Medical technology officer	1 to 5	21[c]	8	169
Microbiologist	C	45[c]	3	134
Medical laboratory scientific officer	2	22[c]	8	173
Chief pharmacist	F to H	39[c]	4	156
Senior physiotherapist	Senior 1 to 2	24[b]	3	72
Nurse specialist	G	22[b]	9	198
Clinical tutor		33[d]	6	196
Nurse practitioner	G	22[b]	17	374
Trainee				
Nurse practitioner in training	G	22[b]	93	2046
Total				**6193**
Annuity factor (6%, 15 years) 9.71				
Annual equivalent cost of training scheme				**638**
Lower limit (30 years, 50% training costs)				225
Upper limit (5 years, 200% training costs)				2940

[a] *Actual cost based on midpoint salary of grade(s) specified. For consultants, this includes allowances for discretionary points and distinction awards*
[b] *From Netten & Curtis.[22] Cost includes salary, oncosts, qualifications, ongoing training and overheads*
[c] *Salary information from <http://www.nhscareers.nhs.uk/> January 2000. Oncosts and other overheads estimated assuming the same overhead/salary ratio as for nurse specialist*
[d] *Academic salary estimate. Oncosts and other overheads estimated assuming the same overhead/salary ratio as for nurse specialist*

medications or were admitted to hospital. Diary information was collated at each 6-monthly outpatient review. Outpatient drug prescriptions were validated from medical records. Resource use that was clearly unrelated to bronchiectasis was excluded from the cost analysis.

In order to estimate the cost of the training programme, the nurse practitioner recorded the time spent attending tutorials, clinics, and ward rounds (see *Table 5*). The cost of this time was based on the salary, oncosts and overheads of the trainer and trainee.[22] As training is a fixed cost, providing benefits beyond the 2 years of this study, this cost was annuitised, with a 6% discount rate, over the estimated working life of a nurse practitioner.[23] At Papworth Hospital, the span of this working life was estimated to be 15 years and this figure was used in the primary analysis. It is recognised that both the extent of the training programme and the estimated working life span of the nurse practitioner will vary greatly from one setting to another. In a sensitivity analysis, the importance of each assumption was examined by rerunning the cost analysis with plausible upper and lower limits for these variables (*Table 5*).

The cost of supervising the nurse practitioner was difficult to calculate accurately, as the trial protocol required more frequent supervision meetings than would be necessary in clinical practice. Hence, in the primary analysis it was assumed that the amount of ongoing supervision that the nurse practitioner would require would be similar to that required for a specialist registrar.[22] Specialist registrars frequently rotate through the lung defence clinic and require a high level of supervision; hence, this assumption may overestimate the supervision requirements of the nurse practitioner in the long run. Again, the importance of this assumption was tested in the sensitivity analysis, in which the extent of ongoing supervision and training requirements was varied from 50% to 200% relative to a specialist registrar.

TABLE 6 *Unit cost estimates for consultants, special registrars and the nurse practitioner*

Resource	Costs (£)				
	Consultant[a]	Specialist registrar[a]	Nurse practitioner[a]	Nurse practitioner	
				Lower limit	Upper limit
Salary	64,918	35,962	22,108	22,108	24,748[d]
Salary oncosts	8,908	4,312	2,456	2,456	2,749
Qualifications	32,332	26,525	4,997	4,997	6,456
Nurse practitioner training course	N/A	N/A	638	225	2,940
Overheads (indirect + administrative)	22,912	22,912[b]	22,912[b]	22,912[b]	22,912[b]
Ongoing training	1,283	2,715	2,715[c]	1,358	5,430
Capital overheads	3,946	3,946[b]	3,946[b]	3,946[b]	3,946[b]
Total (adjusted for non-London multiplier)	**125,095**	**89,823**	**55,785**	**£54,138**	**64,536**
Working hours per year	1,640	1,802	1,640[b]	1,802[c]	1,575[b]
Proportion of direct patient contact	0.69	0.69[b]	0.69[b]	0.8[a]	0.69[b]
Cost per patient-related hour	**111**	**72**	**49**	**38**	**59**

[a] *Based on Netten & Curtis*[22]
[b] *Assumed to be same as for consultant*
[c] *Assumed to be same as for the specialist registrar*
[d] *Midpoint grade H, including discretionary points (Nurses' pay information, April 1999. Department of Health, London)*
N/A, not applicable

As this study took the perspective of the NHS, no attempt was made to track most non-health service costs, such as social service use, patient expenses and informal care costs.[24] There was no evidence to suggest that the introduction of a nurse practitioner would lead to cost shifting from the NHS to social services or patients. The exclusion of these non-health service costs is considered to have had little impact on the analysis. As part of the secondary analysis, the lengths of time that patients took off normal work because of their bronchiectasis were monitored – including both work outside the home and housework. The cost of lost productivity might vary between nurse practitioner-led and doctor-led care if either resulted in reduced patient morbidity. Several methods have been proposed for valuing time off work but there is poor consensus about the best valuation method.[24] In this study, the mean number of days off work in both intervention groups are presented.

Source of unit costs

The cost of a doctor-led clinic was based on published unit costs for the patient-related time of medical consultants and specialist registrars.[22] These costs include salary, distinction awards, oncosts, qualifications, ongoing training and overheads. The same method was used for nurse practitioner-led clinics; initially the nurse practitioner was assigned a mid-point grade G salary (*Table 6*).[22] It was assumed that the overheads and proportion of time spent on patient-related activity would be the same for the consultant, the specialist registrar and the nurse practitioner, as they all shared the same examination areas and provided similar services for the patients in this study. The sensitivity analysis tested the effect of grade, qualifications, working hours, ongoing supervision and proportion of direct contact time on the unit cost estimate for the nurse practitioner (*Table 6*). Higher nursing grades may be particularly relevant in future years as nurse-consultant posts become established. Papworth Hospital finance department provided unit costs of tests, procedures and patient admissions. Published unit costs were used for admissions to other hospitals,[25] drugs,[26] and primary care consultations.[2] A full list of unit costs is provided in *Table 7*. All costs are reported in 1999/2000 values and, as they were only followed for 1 year, the costs were not discounted.

External validity

Most economic analyses presuppose that any resources freed by an intervention are redeployed in the long run in the most productive alternative

TABLE 7 *Unit costs*

NHS resource	Unit cost (1999/2000) (£)	Source
Fixed costs		
Training programme	638 per annum	See *Table 5*
Per patient costs		
Consultant-led clinic	111 per hour	See *Table 6*
Specialist registrar-led clinic	72 per hour	See *Table 6*
Nurse practitioner-led clinic	49 per hour	See *Table 6*
Drugs	Cost per item	*Monthly Index of Medical Specialities*[26]
Investigations and procedures	Cost per item	Papworth Hospital
Ward stay (hotel cost per day)		
Medical ward	206	Papworth Hospital
Intensive care unit	645	Papworth Hospital
Surgical ward	267	Papworth Hospital
Medical day case	385	Papworth Hospital
Surgery day case	290	Papworth Hospital
Sleep support centre	288	Papworth Hospital
Other hospital	Cost per item	NHS Executive[25]
GP visits		
Surgery	18	Netten & Curtis[22]
Home	45	Netten & Curtis[22]

use. For example, in the context of this study, it is assumed that any senior medical staff time released by the nurse practitioner will be used productively in the treatment of new and existing patients. This may be a straightforward assumption, given the long waiting lists for most outpatient services; however, it should be verified before the results of this economic analysis can be generalised to other clinical settings.

Main findings

Complete resource-use data were available for all patients from randomisation until the end of the trial ($n = 78$) or until the date of death ($n = 2$). The main results of the economic analysis are presented in *Table 8*. Although the unit cost of the nurse practitioner was less than half that of the consultant (*Table 7*), this did not lead to a large reduction in the cost of outpatient visits (*Table 8*). This was due in part to more frequent visits for patients being cared for by the nurse practitioner. During doctor-led care, patients had an average of 4.5 outpatient visits compared with an average of 5.1 visits under nurse practitioner-led care. Some consultations scheduled for the nurse practitioner were actually conducted by doctors because six patients did not cross over to nurse practitioner-led care because of revised management plans. Consultations with the nurse practitioner lasted longer than consultations with specialist registrars or consultants: for the 563 consultations for which time was recorded, the mean duration in a nurse-led clinic was 27 minutes compared with 20 minutes in a doctor-led clinic (t-test; $p < 0.001$). These factors counterbalanced the lower unit cost of the nurse practitioner.

With the exception of GP visits, the nurse practitioner incurred greater costs in all other resource use indicators. This was especially evident for patient hospital admissions (£861 greater), intravenous antibiotics (£356 greater) and oral antibiotics (£161 greater). Hospital admissions occurred more frequently under nurse practitioner-led care and, on average, lasted longer than those initiated by doctors (10.6 vs. 7.0 days: t-test; $p = 0.034$). It should be noted, however, that once admitted to hospital, the care patients received was exclusively doctor-led.

Three drugs accounted for over 80% of the difference in antibiotic use (*Table 9*). Intravenous meropenem and ceftazidime were not prescribed frequently but the high unit cost of both drugs ensured that the slightly increased use in patients being cared for by the nurse practitioner was economically important. Intravenous antibiotic use must be pre-authorised by medical staff, so this difference in cost is not the result of an autonomous decision by the nurse practitioner. The third drug was nebulised colistin – an antibiotic with a moderate unit cost prescribed for

TABLE 8 *Economic analysis*

Resource	Nurse practitioner-led arm (*n* = 80)		Doctor-led arm (*n* = 80)		Difference (SD) (£)
	Mean number per patient	Mean cost per patient (£)	Mean number per patient	Mean cost per patient (£)	
Nurse practitioner-led clinic visits	4.61	180	0	0	180 (158)
Doctor-led clinic visits	0.45	25	4.48	217	–192 (199)
Procedures	0.13	61	0.11	54	7 (376)
Imaging	1.14	47	0.76	45	1 (112)
Other tests	24.58	260	18.94	222	37 (257)
Antibiotics (intravenous)	23 days	879	16 days	523	356 (1452)
Antibiotics (oral)	222 days	684	201 days	524	161 (695)
Bronchodilators	461 days	213	435 days	193	20 (179)
Corticosteroids	238 days	278	219 days	258	20 (181)
Other drugs	212 days	180	190 days	155	25 (194)
Inpatient	6.46 days	1338	2.36 days	477	861 (2755)
Day case	0.11	43	0.05	16	27 (170)
GP visits	1.11	20	1.40	26	–6 (33)
Total		4208		2711	1498 (688 to 2674)[a]

[a] *95% CI non-parametric bootstrap bias corrected method; 5000 replicates*

patients with pseudomonas infection according to a well-defined protocol. The nurse practitioner prescribed colistin more frequently than the rest of the clinical team, which probably indicates that she was following the treatment protocol more rigorously. Because of the requirement for her to record prescriptions and tests issued at clinic, it is considered that the nurse practitioner was more likely to have ensured that patients left with supplies of standard treatment such as colistin. If doctors had a greater awareness of hospital budgeting restraints, they may have shifted some of the cost of colistin on to GPs. Drugs issued in primary care were tracked in the patient diary and are included in *Table 9*; however, patient self-reports tend to underestimate medication utilisation[27] and this may have accentuated the differences between doctor-led and nurse practitioner-led care.

There was little difference in the total cost of tests and procedures between nurse practitioner-led and doctor-led care. However, the nurse practitioner did use several low-cost routine tests (e.g. sputum micro, culture and sensitivity and C-reactive protein) more frequently than the rest of the team (*Table 10*). Less frequently used but more expensive procedures (e.g. lobectomy, bronchoscopy, oesophagoscopy and thoracoscopy) were more evenly distributed between the two forms of care.

Overall, nurse practitioner-led care resulted in significantly higher costs per patient compared with doctor-led care (£1498; 95% CI, 688 to 2674) (*Table 8*). This was largely due to the differences in hospital admission rates and intravenous antibiotic costs. As FEV_1 outcomes after nurse practitioner-led and doctor-led care were equivalent, a cost-minimisation analysis was considered sufficient.

The distribution of cost differences shown in *Figure 6* demonstrates that many patients had very similar costs under both forms of care. Three patients with much greater costs (> £10,000) in the nurse practitioner-led phase of the study were clear outliers. All three patients were randomised to the nurse practitioner in the first year of the study, had multiple hospital admissions and intravenous antibiotics. In the second year, during the doctor-led phase of their care, two of these three patients had shorter hospital admissions including intravenous antibiotic treatment. One of these three patients died before the end of the second year. In total, these three patients accounted for approximately 50% of the observed difference in cost between nurse practitioner-led and doctor-led care.

Eight patients did not remain in their randomly allocated care group throughout the study – six

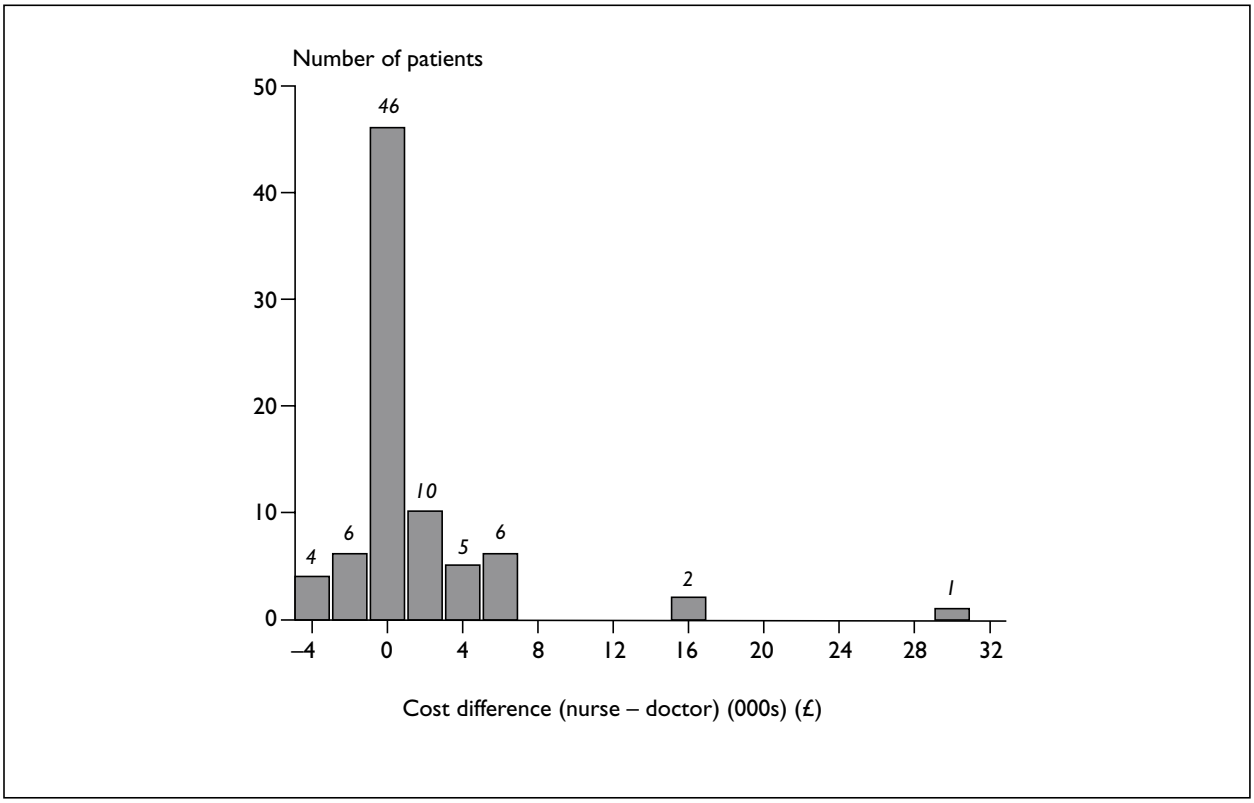

FIGURE 6 *Distribution of paired cost differences*

patients did not cross over to nurse practitioner-led care because of revised management plans and two patients died before the end of the study. Exclusion of these eight patients did not affect the economic analysis. The total cost of nurse practitioner-led and doctor-led care remained stable (£4198 versus £2742).

Sensitivity analysis

The results are not sensitive to any of the assumptions used to estimate the training cost of the nurse practitioner (*Table 11*). The training programme is a fixed cost that yields benefits over a number of years and, within each year, contributes toward the care of many patients at numerous clinics. Thus, even if the training programme was much more intensive and costly in the short run, the long-term impact on costs per patient would be minimal. Similarly, plausible changes to the working conditions of the nurse (e.g. higher grade, higher patient contact time, longer/shorter hours) would have little impact on the overall patient cost of nurse practitioner-led care. Even when all these variables are combined into best and worst case scenarios (*Table 11*), the effect on cost is insignificant. In all cases, differences in these fixed costs are dwarfed by patient level variables, such as prescribing and hospital admissions.

The implication of these findings is clear; it is worth spending extra resources on the training programme in the short run if, as a result, nurse practitioner prescribing and care can be made more cost-effective.

Non-health service costs

No information was collected on patient out-of-pocket expenses. Nevertheless, it is evident from *Table 8* that patients under nurse practitioner-led care will have incurred higher travel costs because, on average, they attended more outpatient clinics (5.1 versus 4.5). Papworth Hospital provides a regional service, so these extra travel costs might be important to individual patients. However, it is very unlikely that these travel costs would alter our interpretation of the results. The equivalence of the primary outcome, FEV_1, and the similarity in the secondary functional and quality-of-life outcomes indicates that other non-health service costs, for example, home care, would probably be similar for both the year of nurse practitioner-led care and that of doctor-led care. Patients reported fewer days taken off usual work while in the nurse-led period of the study; however, the difference was not statistically significant (*Table 12*).

TABLE 9 *Drug utilisation comparison*[a]

Drug name	Route	Typical daily dose	Number[b]		δ cost (£)[c]
			Nurse-led care	Doctor-led care	
Ceftazidime	i.v.	3000 mg	37	21	190
Meropenem	i.v.	3000 mg	13	4	148
Colistin	Nebuliser	2 million units	67	49	146
Tobramycin	i.v.	360 mg	56	39	20
Ciprofloxacin	Oral	1500 mg	151	138	12
Omeprazole	Oral	20 mg	21	18	10
Lansoprazole	Oral	30 mg	11	4	8
Doxycycline	Oral	100 mg	64	46	7
Eformoterol	Aeroliser	24 µg	10	8	4
Ipratropium/salbutamol	Nebuliser	3 mg/15 mg	9	7	4
Salmeterol	MDI	100 µg	24	23	4
Prednisolone	Oral	1 mg	188	198	4
Tobramycin	i.v.	60 mg	28	21	2
Montelukast	Oral	10 mg	6	5	2
Beclomethasone diproprionate high dose	MDI	1000 µg	25	21	2
Fluticasone	Spray	400 µg	4	6	2
Gentamicin	Nebuliser	160 mg	7	7	2
Clarithromycin	Oral	500 mg	49	50	1
Budesonide	MDI	400 µg	7	7	1
Ipratropium	MDI	160 µg	11	9	1
Amoxycillin	Oral	750 mg	57	41	1
Terbutaline	MDI	2000 µg	5	5	0
Co-amoxiclav	Oral	1125 mg	10	11	0
Loratadine	Oral	10 mg	6	4	0
Influenza vaccine	i.m.	1 unit	12	12	0
Theophylline	Oral	400 mg	9	4	0
Ipratropium/salbutamol	MDI	160/800 µg	7	4	0
Salbutamol	MDI	800 µg	31	27	0
Pneumococcal vaccine	i.m.	1 unit	3	7	0
Budesonide	Turbohaler	400 µg	11	9	–1
Beclomethasone	Spray	400 µg	16	13	–1
Oxytetracycline	Oral	2000 mg	2	11	–2
Salbutamol	Nebuliser	5 mg	11	14	–3
Fluticasone high dose	MDI	1000 µg	21	20	–26

[a] *This table excludes drugs prescribed fewer than ten times during the course of the trial*
[b] *Indicates total number of times drug was started anew; excludes some continuous repeat prescriptions*
[c] *Per patient difference in cost (nurse practitioner cost – doctor cost)*

i.v., intravenous; i.m. intramuscular; MDI, metered-dose inhaler

Interpretation

The absolute magnitude of the cost difference was not constant throughout the course of the trial and should be interpreted carefully. Treatment costs by year are depicted in *Figure 7*. The mean cost of nurse practitioner-led care was much higher in the first than in the second year of the trial (£5202 versus £3262). In contrast, the cost of doctor-led care remained relatively stable between the first and second periods of the trial. During the second year of the study, the disparity between the costs of nurse practitioner-led and doctor-led care was much less than the overall mean cost difference indicates. This suggests that there may have been interaction between the nurse practitioner treatment costs and the period of the study.

Two simple tests to assess the statistical significance of treatment by period interaction have been proposed.[28,29] However, both rely on the two-sample *t*-test and are known to be insensitive

TABLE 10 *Test/procedure uilisation comparison*[a]

Test/procedure	Number		δ cost[b] (£)
	Nurse-led care	Doctor-led care	
Lobectomy	2	0	30
Sputum microscopy, culture and sensitivity	333	250	16
Chest X-ray (posteroanterior and lateral)	74	40	14
Tobramycin levels	185	119	10
Bronchoscopy	3	2	6
C-reactive protein	172	108	6
Flow volume loop	44	24	5
Spirometry	32	11	5
Electrocardiogram	18	11	4
Sputum AAFB (respiratory gram and culture) smear	29	8	4
Oesophageal manometry	2	1	4
Oesophageal dilatation	1	0	4
Urea and electrolytes	211	145	3
^{99m}Tc MIBI [methoxyisobutyl isonitrile] stress test	1	0	3
TB culture and microscopy	15	2	3
Barium swallow	3	1	2
Full blood count	220	166	1
VO_2 max	1	0	1
Methicillin-resistant *Staphylococcus aureus* swab	11	2	1
Treadmill exercise test	1	0	1
Erythrocyte sedimentation rate	132	93	1
Colistin trial	3	2	1
Gentamicin levels	10	0	1
Theophylline levels	12	7	1
X-ray, hands	2	0	1
Ultrasound of calves	6	4	1
Liver function tests	122	108	1
Full respiratory function	1	0	1
Midstream urine	13	4	0
Magnesium	30	9	0
Coagulation screen	9	5	0
Blood film	8	2	0
Nose and throat swab	8	5	0
Glucose	29	24	0
Gammaglobulin	24	22	0
Bone profile	20	20	0
Antineutrophil cytoplasm antibody	16	16	0
Influenza antibody	5	5	0
12-minute walk	79	80	0
CH_{50} immunology marker test	3	7	−1
Meningococcal antibody	0	3	−1
Thyroid function	12	18	−1
Aspergillus precipitans	6	10	−1
Immunoglobulin G subclasses	6	8	−1
Immunoglobulin E	11	20	−1
Leucocyte phenotype	0	1	−1
Autoantibody	25	36	−1
Haemophilus influenza type B antibody level	0	4	−1
Radioallergosorbent test for *Aspergillus*	12	20	−1
Tetanus antibody	4	8	−1

continued

***TABLE 10* contd** *Test/procedure uilisation comparison*[a]

Test/procedure	Number		δ cost[b] (£)
	Nurse-led care	Doctor-led care	
Skin allergy test	1	8	–2
Immunoglobulins	7	22	–2
Lung biopsy	0	1	–2
Pneumovax antibodies	14	25	–2
Echo	2	6	–2
Angiogram	1	2	–7
T-lymphocyte subsets	8	19	–8
Neutrophil phenotype	4	13	–10
Oesophagoscopy	0	2	–12
Thoracoscopy	0	1	–14
CT scan	8	17	–15

[a] *This table excludes tests and procedures ordered fewer than ten times during course of trial and where difference in cost < £1*
[b] *Per patient difference in cost (nurse practitioner cost – doctor cost)*

TABLE 11 *Sensitivity analysis: nurse practitioner costs*

Scenario	New value	δ cost[a] (£)	Change in cost (%)
Main analysis (base case)		1498	
One-way analyses			
Longer working life[b]	30 years	1497	0
Shorter working life[c]	5 years	1499	0
Higher training cost[c]	200%	1499	0
Lower training cost[b]	50%	1497	0
Higher grade[c]	H	1502	0
Higher level of ongoing training[c]	200%	1502	0
Lower level of ongoing training[b]	50%	1495	0
Longer working hours[b]	1802 per annum	1488	1
Shorter working hours[c]	1575 per annum	1502	0
Higher percentage of direct patient contact time[b]	80%	1484	1
Multi-way analyses			
Best case (low nurse practitioner costs)		1473	2
Worst case (high nurse practitioner costs)		1519	1

[a] *Per patient difference in cost (nurse practitioner cost – doctor cost)*
[b] *Included in best-case scenario*
[c] *Included in worst-case scenario*

in many circumstances.[28] Given the moderate sample size and the high variability in costs observed in this trial, it is not surprising that neither test detected any treatment cost by period interaction (*Figure 7*). The apparent decrease in the cost of nurse practitioner-led care over time might be caused by three factors:

(i) learning effects
(ii) selection effects
(iii) carryover effects.

Perhaps the most straightforward explanation for the observed data is that, over time, the nurse became more accustomed to the practitioner role. A learning curve has been observed in many other areas of medicine[30] and is certainly plausible in this situation. The data suggest that, if a learning effect was present, it was most prominent for routine prescriptions. During the second period of the trial, the cost of nurse practitioner prescriptions of oral antibiotics, bronchodilators, corticosteroids and other

(non-intravenous) drugs was very similar to the cost in the doctor-led arm of the study. Most of the cost difference that remained in the second year was due to hospital admissions and intravenous antibiotic prescriptions.

Alternatively, the decreased cost of nurse practitioner care in the second period may be a result of a selection effect. Of 41 patients, six (15%) did not cross over to nurse practitioner care because of revised management plans. If all 41 patients had crossed over to nurse practitioner-led care as planned, then the mean treatment cost in the second year of the study might have been higher. The selection effect is, at most, only a partial explanation, because the number of patients involved is small. A 100% increase in the treatment cost of these six patients would lead to only a 10% increase in the mean cost of all 41 patients who were scheduled to receive nurse practitioner-led care in the second year.

One further possibility is that treatment during the first year of care may have had a carry-over effect on the subsequent costs of care in year two. For example, the nurse practitioner in year two may have dealt more efficiently with patients who had care plans firmly formulated by doctors over the first year of the study. Alternatively, the treatment of pseudomonas infection by the nurse practitioner in the first year may have led to reduced occurrence of infection and admissions to hospital in year two during doctor-led care in this same patient group. However, there were no differences in clinical outcomes at 12 or 24 months. Hence, it is considered that any carry-over effect was minimal.

TABLE 12 *Number of days off usual work*

	Nurse practitioner-led care	Doctor-led care	*p*-value[a]
Mean number of days off work (SD)	7.9 (10.5)	9.8 (12.8)	0.095

[a] *Paired samples t-test*

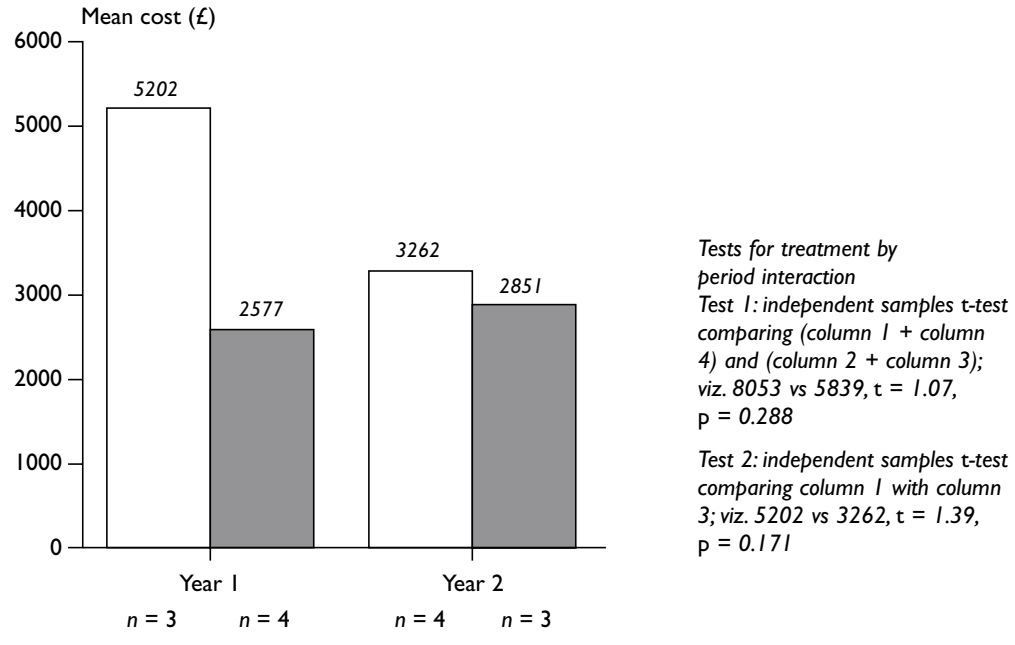

FIGURE 7 *Treatment costs by study year (□, nurse practitioner-led care; ■, doctor-led care)*

Chapter 5

Discussion and conclusions

Discussion

This study has demonstrated that nurse practitioner-led and doctor-led outpatient care is of equivalent effectiveness for stable patients with moderate to severe bronchiectasis and established management plans.

An attempt was made to identify any small changes in clinical and health-related quality-of-life outcomes by using an efficient study design; a crossover design concentrates on within-patient change and is, therefore, sensitive to change. Since within-patient variance is usually much smaller than between-patient variance, crossover designs require fewer patients to detect clinically significant differences. It is also entirely appropriate for patients with chronic diseases, for whom outpatient clinics deal with controlling symptoms and complications rather than acute, short-lived interventions. In addition, the study concentrated on important and sensitive markers of change in health status. Indices of lung function, such as FEV_1 and FVC, are measured to within 5%.[31] Nurse practitioner-led care has been shown to maintain lung function within 2.0% (upper limit of 95% CI) of doctor-led care, which is well within the limits of random fluctuation. Similarly, the CRIQ[17] and the St. George's Hospital Respiratory Questionnaire[18] have been validated in patients with chronic lung disease and have proved sensitive to changes in function. Dimension scores for these questionnaires for patients undergoing nurse practitioner-led care were not significantly different from doctor-led care. If anything, there was a small trend towards better patient-reported quality of life following nurse practitioner-led care.

The only demonstrable difference in clinical outcomes was the number of hospital admissions. There were more patient admissions under nurse practitioner-led care, although the readmission rates for bronchiectasis-related problems were not significantly different. This suggests that, overall, the nurse practitioner may have been more cautious by recommending hospital admission more often. All admissions to hospital are authorised by a consultant and, on review, none of the admissions recommended by the nurse practitioner were deemed inappropriate. The rate of hospital admissions for any reason was 0.83 per patient-year for the nurse practitioner compared with 0.54 for the doctors. The corresponding rates for chest admissions were 0.54 and 0.30 per patient-year, respectively. These admission rates are low for bronchiectasis and the authors consider it unlikely that the nurse practitioner was substantially overcautious in this respect.

As these patients were receiving evidence-based medicine relating to this specific chronic lung disease in a specialist clinic, one would expect that the satisfaction rate would be high. However, statistically significant differences were found in favour of the nurse practitioner in patients' ratings of satisfaction with the consultation, and in the areas of communication and time spent with the patient. The clinic data confirmed that the nurse practitioner was spending longer with patients and, hence, raised satisfaction levels could be expected. In previous studies in primary care, this patient preference for nurse practitioner-led care has been confirmed and has led to suggestions that the lower hourly cost of the nurse is offset, to some extent, by longer consultation times[32–34] and more frequent visits.[32] Similarly, in this study the nurse practitioner spent longer with patients and saw them slightly more frequently. It is not clear whether this trend will persist over time, as nurse practitioners become more experienced or take on a larger workload.

Patient compliance with prescribed therapy is a vital component of the successful management of chronic disease. In this study, patients were asked to report on their compliance with physiotherapy and drug therapy. Overall, self-rated compliance levels were high and, in compliance with antibiotic treatment, a statistically significant difference was found between the two modes of care in favour of the nurse practitioner. The extent of compliance with antibiotic therapy will have an affect on the rate of exacerbations of infection and, thus, on resulting prescriptions and hospital admissions and their costs; future studies of this type should therefore be sure to include measures of compliance.

In this study, the nurse practitioner used more resources than the medical team, mainly because

of increased admissions and the use of antibiotics. Intravenous antibiotics prescriptions and hospital admissions must be authorised by medical staff and, in every case, they were considered appropriate. The nurse practitioner's training was determined by a single consultant. Hence, the cost difference may simply reflect variation between individual doctors' practices. Other medical staff may have different thresholds for patient admissions. Over 80% of the difference in costs for antibiotics resulted from the use of three drugs in a small number of patients. Two of these drugs were administered intravenously, a practice that needed medical authorisation and so is assumed to have been appropriate. The third was prescription of colistin nebulisers, according to guidelines for the treatment of pseudomonas. This may indicate that the nurse practitioner was more likely to follow the guidelines, particularly during the first year, and perhaps less likely to rely on GPs to provide such drugs for these patients. One weakness of this study is that all prescriptions issued by GPs may not have been documented, since patients were required to record this information. Clearly, it is important to continue to monitor prescribing practice and hospital admission thresholds over time. This should quickly highlight any areas in which the nurse practitioner requires further training.

There was some evidence of a learning effect over time, in that the nurse practitioner incurred fewer costs in the second year than in the first. The cost of nurse practitioner-led care per patient was £5202 in the first year compared with £3262 in the second. The cost for doctor-led care was £2577 in the first year and £2851 in the second. Since some patients did not cross over to nurse-led care, the learning effect cannot be delineated clearly from a selection effect. However, the extent of convergence suggests that costs for nurse-led care can be brought into line with those for doctor-led care. If the increase in costs incurred by nurse-led care can be limited to the first year, it may be considered worthwhile, since it may free up the consultant to see new, and clinically demanding, patients.

Sensitivity analysis showed that cost estimates were robust to changes in assumptions regarding training, supervision and costs of the nurse practitioner. Any changes to these assumptions were heavily outweighed by the observed differences in prescribing and admissions.

The first phase of this study involved preparation of the nurse practitioner for her extended role, since appropriate training was considered central to patient safety and to the outcome of the trial. Since the late 1980s, the role of the clinical nurse specialist in respiratory medicine has evolved to provide support, education and community liaison for patients with acute and chronic respiratory diseases. The respiratory nurse specialist's flexible approach to patients' needs has included involvement in developing both patients' and carers' understanding of the respiratory disorder. The role of the respiratory nurse specialist in visiting patients with respiratory disability has demonstrated an improvement in survival at a potential increase in cost to the health service.[35]

The nurse practitioner participating in this study completed a nurse practitioner degree study programme that provided the essential theoretical underpinning necessary for making professionally autonomous decisions: to evaluate undifferentiated and undiagnosed problems, to assess the patients' healthcare needs using physical examination skills, to screen patients for disease risk factors and early signs of illness, to provide counselling and health education, and to have the authority to admit or discharge patients, or refer them to other healthcare providers. In order to practise independently, the nurse practitioner needed to acquire a detailed theoretical knowledge of bronchiectasis and its management, together with practical experience and skills in clinical assessment and therapeutics. In addition to the degree course, therefore, a specific training programme was devised, to educate the nurse in the optimum management of this complex chronic disease. Since the individual who took up this post already had previous training and experience in some areas, this took only 6 months to achieve, although it is expected that such training could last for 9–12 months. The successful completion of appropriate training is considered a vital prerequisite to the development of the role; the combination of degree course and specific training meant that the nurse practitioner attained a level of advanced nursing practice which encompassed history-taking, clinical examination and assessment, prescribing and the altering of patient management – all dictated by the patient's condition and the guiding principles of the clinic.

Early descriptive studies of the nurse practitioner role that evaluated safety, management competence and patient satisfaction were promising.[3–7] However, these studies were flawed by a lack of appropriate controls, small sample sizes, lack of randomisation, failure to account for differences in severity of illnesses and failure to measure outcomes.[8] In addition, concerns have been

expressed about the validity of early American studies being applied in a UK setting.[9] In the UK, RCTs of nurse specialist-led versus doctor-led care have been published in neurosis,[36] stroke patients,[37] rheumatology,[38] Parkinson's disease[39] and, in primary care, for out-of-hours telephone consultations[40] and same-day appointments.[32–34] However, with the exception of the primary care nurse, none of these roles extended beyond the traditional nursing domain. Although respiratory nurse specialists are well established,[35] to date their role has been predominantly in patient support and education, and community liaison. In this study, expanding the nurse practitioner role to include outpatient follow-up of chronic respiratory patients provided an effective and acceptable method of delivering care in a hospital outpatient setting. To our knowledge, this is the first published RCT of a nurse practitioner role in secondary/tertiary care, which, in the UK, has a greater medico-technical component than the nurse specialist.

The extent to which this study can be extrapolated to other clinics requires discussion. The study involved a single nurse practitioner in one bronchiectasis clinic at one hospital. Of the 41 patients assigned to doctor-led care in the first year, six (15%) could not be transferred to nurse practitioner-led care for the second year. These patients developed other medical problems that required additional medical investigation, intervention and management beyond the scope of the training of the nurse practitioner. In the absence of a formal trial, the patients may still have seen a nurse practitioner for their bronchiectasis but, in keeping with the strict safety code laid down by the research protocol, it was agreed that they should not be allowed to cross over to nurse practitioner-led care. It is possible that inclusion of these six patients introduced some bias but the extent of this should be minimised by our use of intention-to-treat analysis. The primary analysis was repeated excluding these patients, with almost identical results (note: these data are not presented here). The authors would reinforce the message that the results of this trial are not generalisable to patients who have no established treatment plan.

Although the treatment and management of the study patients are broadly generalisable to other chronic disease clinics, the extrapolation of the results to acute onset diseases or diseases in which presentation and/or complications are wide-ranging or rapidly changing, such as, for example, malignant disease, is not recommended. The nurse practitioner in this study had long experience of working with cardiothoracic patients in a tertiary centre, was at a senior level (Grade G/H), and was educated to degree level. It is considered that both academic and professional competence have been important in the successful development of this role. It is worth reflecting that in such a specialised clinic setting, where the comparison was with a small team of consultants and speciality-trained registrars rather than senior house officers, the demonstration of equivalence was a significant personal achievement for the nurse practitioner concerned, who has since been appointed as the hospital's first nurse consultant.

The optimal timing of an evaluation of a new role is always tricky. In considering the design of future studies of this type and how to allow for the possible learning curve effect, perhaps successful role development should be considered in four stages: training; a period of establishing safe practice under close supervision; a formal evaluation; and a period of audit to ensure that standards are being maintained. One potential problem is that the role becomes so well established during the first two stages, or at least current practice is so diluted, that a formal evaluation in a randomised study is not pursued. For the primary outcome measure, the length of the learning curve was accurately predicted and this was covered by the training period. For hospitalisation, prescriptions and costs, the learning curve appeared to extend beyond the training period, which had not been predicted. Thus, randomisation during training, and a formal evaluation of all outcomes immediately after training, would have helped to identify and rectify the prolonged training needs in these areas. An alternative approach would be to simply lengthen the trial to include the first three stages of development; this would mean lengthening the period of randomisation, which is not a problem in circumstances in which a difference between groups is not being sought. Wider discussions of the design options for trials in which a learning curve effect is a potential hazard are to be encouraged. A recent report of work in this area may help to inform further debate.[41]

The NHS plan[42] and the modernisation agenda call for a partnership approach to managing services and dealing with 'pressure points' in order to gain maximum health benefits. In the *National Service Framework for coronary heart disease*[43] the approach is to seek clear protocols for better interface between different professional groups and different care settings to ensure faster access for patients to the most appropriate clinical care.

The development of nurse practitioner roles and nurse consultants has the potential to help in relieving 'pressure points' and in providing faster, cost-effective access to high-quality care. During the period of this study, there was only one weekly clinic available and this was fully booked, with little scope for emergency patients to be reviewed. With resources in general practice fully stretched, patients with bronchiectasis who suffer recurrent chest infections can become severely unwell within 24 hours. By providing additional nurse practitioner-led clinics since completion of this study, such emergency returns to the clinic can now be accommodated within 24 hours, potentially reducing the risk of deterioration in a patient's function. In addition, the nurse practitioner is providing education, support and advice between visits via telephone contacts, helping patients to retain both their independence and a closer degree of control over their disease and its management.

The benefits and costs of introducing an advanced nurse practitioner to the clinical team need to be considered over the long term. The potential benefits to patients in shortening waiting times and increasing satisfaction with care, and possibly compliance with care, need to be set against the initial increase in costs of the extra investigations and prescriptions involved in seeing more patients more quickly. However, over a longer period, the addition of a nurse practitioner to a team could conserve resources by reducing the need to employ extra consultant physicians and specialist registrars to deal with increasing patient numbers. The wider issues relating to training large numbers of nurse practitioners – in terms of availability and cost – need to be considered as part of an overall strategy for the development of the NHS workforce. However, if quality is the driving priority in the context of increasing demand, then it is clear that such role development needs to be considered and evaluated carefully.

Conclusions

1. It has been demonstrated in this study that, within the context of an RCT of crossover design, nurse practitioner-led care for stable patients within a chronic chest complaint clinic is safe and as effective as doctor-led care. Not only were there negligible differences in the important clinical and quality-of-life measures but also the CIs were small enough to exclude, with high probability, any detrimental effect of introducing nurse practitioner-led care.
2. Patients requiring routine monitoring and minor modifications to therapy were managed by a trained nurse practitioner, to a high level of satisfaction for both patients and their GPs.
3. There was significant additional resource use during nurse practitioner-led care. This difference was substantially greater in the first year and may be corrected or reduced by focusing training in the areas of greatest difference in practice.
4. Prospective collection of resource-use data alongside a randomised trial is a valuable method of monitoring nurse practitioner-led care and identifying important variations in practice that require additional discussion or supervision.
5. The development of this type of role has the potential to contribute to the aims of the NHS Plan and Service Frameworks in terms of increasing teamwork, both within the hospital setting and across the hospital–community interface, between the various professionals involved in their care and the patients.
6. With the inclusion of a fully trained and experienced nurse practitioner in the clinical team, there is potential for more consultant time to be spent increasing the throughput of new patients, reducing waiting times and ensuring that care is optimised and treatments reassessed.
7. The study design, a randomised, controlled crossover trial based on the use of equivalence in the outcome of care, proved robust and appropriate for this type of evaluation.

Recommendations for research

1. Similar evaluations should be considered as part of the process of introducing nurse practitioner roles or any role transfer in the health service, as much can be learned from the results in terms of ensuring that their introduction is both acceptable to patients and cost-effective. As demonstrated here, cost-effectiveness cannot be assumed in circumstances in which a nursing grade practitioner is taking on a role previously filled by a medical practitioner.
2. Although the treatment and management of the study patients are broadly generalisable to other chronic disease clinics, the authors would not recommend extrapolation of the results to acute onset diseases or diseases in which presentation and/or complications are wide-ranging or rapidly changing.
3. The combination of appropriate academic and disease-specific study and training, followed by a

period of close supervision and evaluation, is considered to be vital to the effectiveness, acceptance and successful development of extended roles. The implications of these findings suggest that it is worth spending extra resources on the training programme in the short run if, as a result, nurse practitioner prescribing and care can be made more cost-effective.

4. With regard to the design of such studies, there are several recommendations arising from the experience of this evaluation.
   - The crossover design is appropriate and efficient in this trial setting, given the stable, chronic nature of bronchiectasis and the need to identify very small differences in function in the interests of safety.
   - The most important feature in evaluating a new practice is randomisation and this trial was no exception. Randomisation allowed the most objective treatment assignment in the period of study and ensured that unpredicted differences in hospitalisation and cost in the first period were detected. An alternative strategy may have masked these differences.
   - The equivalence approach to the measurement of primary outcome is also to be recommended, since it is unrealistic to expect a nurse practitioner to outperform medical staff and, unless an equivalent standard of care could be established, the role would not be adopted. In addition, equivalence trials are usually larger than trials based on a difference, so that there is good power to detect clinically important differences in secondary outcome measurements. A crossover trial of 80 patients is considered as moderate to large since it relies on within-patient variation and so is sensitive to small changes.
   - To minimise the learning curve effect in future studies of this type, randomisation during training and a formal evaluation of all outcomes immediately after training would help to identify needs and to minimise the learning curve effect during a period of formal evaluation. An alternative approach would be to simply lengthen the trial; this would mean extending the period of randomisation, which is not a problem in circumstances in which a difference between groups is not being sought. Ideally, if the role is adopted, a period of audit should follow to ensure that standards are being maintained and any further training needs identified.
   - This study was powerful enough to show up some statistically significant differences between the two groups in terms of patient satisfaction and patient compliance with therapy – it will therefore be important to include such measures in future evaluations of role transfer.
   - An audit of the throughput and waiting times of new and established patients before, during and after the introduction of a new method of service delivery would add to the discussion of possible additional benefits, in terms of improving access and increasing the efficiency of the particular healthcare setting.

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Contributions of the authors

Noreen Caine, Linda Sharples, Diana Bilton, Mary Keogan and Will Hollingworth developed the trial design, prepared the research protocol and monitored all aspects of the conduct and management of the trial. Jane French was the nurse practitioner and Diana Bilton, Mary Keogan and Andrew Exley were the consultants directly involved in the care of the patients in the trial. The data collection and day-to-day management of the research was the responsibility of Denise Hodgkins. The statistical and economic analyses were conducted by Linda Sharples and Will Hollingworth. All the authors were involved in the preparation of the report.

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Appendix 1

Training programme for nurse specialist in bronchiectasis

Core curriculum

1. What is bronchiectasis? (Consultants)

Principles of the disease
- Incidence, course and prognosis
- Diagnosis
- Clinical presentation
- Investigation
- Session in CT department with consultant radiologist to see high-resolution CT scan

Underlying causes
- Principles of immunological investigation
- Ciliary disorders (including demonstration of ciliary brushing and microscopy viewing of ciliary beating)

2. Associated pulmonary disorders (National Asthma Training Centre course)

Asthma – clinical features
Chronic obstructive pulmonary disease – clinical features
Allergy – rhinitis; sinusitis

3. Pulmonary function (Consultants in Respiratory Physiology)

Theoretical
- Spirometry and peak flow
- Lung volumes – basic principles only
- Gas transfer – basic principles only

Practical
- Training in performing spirometry and peak flow measurement

4. Microbiology of bronchiectasis (Consultant Microbiologist)

- Sputum samples and processing
- Antibiotic sensitivity and resistance
- Antibiotic choice

5. Antibiotic therapy/ therapeutics (Senior Pharmacist)

- Principles of basic pharmacology and pharmacokinetics
- Allergies and side-effects
- Prescribing in bronchiectasis

6. Airway therapy (Consultant Respiratory Physician)

- Bronchodilation therapy – principles
- Inhaler devices and nebulisation therapy – practical
- Inhaled steroids – indications, uses and side-effects

7. Physiotherapy (Senior Physiotherapist)

- Principles of airway clearance
- Modes of chest clearance

8. Assessment of exercise tolerance (Senior Physiotherapist)

- 12-minute walk
- Shuttle

9. Care of intravenous lines (Cystic Fibrosis Sister)

10. Assessment module

11. Research methods (Research & Development staff)

- Basic statistics and research methodology
- Literature searching
- Health-related quality-of-life assessment
- Ethics and confidentiality

Appendix 2

Consultation supervision record form for nurse practitioner or registrar

This document was scanned in from an original document supplied by the authors; this has resulted in a poorer print quality than usual.

Consultation Supervision Record

Please use BLOCK CAPITALS to enter details clearly or if appropriate mark with a cross like this: ☒

Study Number: ☐☐☐

Attach Patient Addressograph label in this box

Routine visit ☐ Other visit ☐ Date : D D / M M / Y Y Y Y

Discussion	**Evaluation by nurse/medic**				**Consultant**	
	Acceptable		Unacceptable		Agree	Disagree
Spirometry	☐		☐		☐	☐
Sputum	☐		☐		☐	☐
General	☐		☐		☐	☐
Admitted	Yes ☐		No ☐		☐	☐
Medications	Changes ☐		No changes ☐		☐	☐
Additional Investigations	Yes ☐		No ☐		☐	☐

Specify/ Action

Assessment

Was advice sought: No ☐ During Clinic ☐ During meeting ☐

Amount of medical time required ☐☐ mins

1. Advice sought appropriately on non-routine matter ☐ 2. Confirmation of correct treatment/action ☐

3. Advice sought on routine matter ☐ 4. Mistake made ☐

Next review ☐☐ weeks

Prescription Sanctioned Yes ☐ No ☐ Change to:

Comments by the Consultant

If uncorrected potential impact of disagreement? Minor ☐ Moderate ☐ Severe ☐

Signature: Nurse/Medical Practitioner _____ Consultant _____ Date _____

Survey : 1009 Page : 1

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Appendix 3

Patient questionnaires: health-related quality of life

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SF-36 Health Survey[a] 40
CRIQ[b] 45
St. George's Hospital respiratory questionnaire[a] 48

[a] Medical Outcomes Trust, Health Institutes, Boston, MA, USA

[b] Office of Research Contracts and Intellectual Property, McMaster University, Hamilton, Ontario, Canada

BRONCHIECTASIS TRIAL

NURSE-LED V DOCTOR-LED OUTPATIENT CARE

SF-36 HEALTH SURVEY

Patient Study ID Number: ☐☐☐

Date: D D / M M / Y Y Y Y

Baseline ☐
6 Months ☐
12 Months ☐
18 Months ☐
24 Months ☐

CONFIDENTIAL

SF-36 HEALTH SURVEY

Instructions: This survey asks for views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.
Please answer every question by marking the appropriate box with a cross like this: ☒
Try to keep your markings inside the box. If you are unsure about how to answer a question, please give the best answer you can.

GENERAL HEALTH

1 In general, would you say your health is: (please mark one box)

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

2 **Compared to one year ago,** how would you rate your health in general **now**? (please mark one box)

- Much better now than one year ago..... ☐
- Somewhat better now than one year ago..... ☐
- About the same as one year ago..... ☐
- Somewhat worse now than one year ago..... ☐
- Much worse now than one year ago..... ☐

HEALTH AND DAILY ACTIVITIES

3 The following questions are about activities you might do in a typical day. Does **your health now limit you** in these activities? If so, how much? (Please mark one box on each line)

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a.	**Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b.	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐
c.	Lifting or carrying groceries	☐	☐	☐
d.	Climbing **several** flights of stairs	☐	☐	☐
e.	Climbing **one** flight of stairs	☐	☐	☐
f.	Bending, kneeling or stooping	☐	☐	☐
g.	Walking **more than a mile**	☐	☐	☐
h.	Walking **half a mile**	☐	☐	☐
i.	Walking **100 yards**	☐	☐	☐
j.	Bathing or dressing yourself	☐	☐	☐

4 During the **past 4 weeks,** have you had any of the following problems with your work or other regularly daily activities **as a result of your physical health**?

(Please mark one box on each line)

		Yes	No
a.	Cut down on the **amount of time** you spent on work or other activities	☐	☐
b.	**Accomplished less** than you would like	☐	☐
c.	Were limited in the **kind** of work or other activities	☐	☐
d.	Had **difficulty** performing the work or other activities (for example it took extra effort)	☐	☐

5 During the **past 4 weeks** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Please mark one box on each line)

		Yes	No
a.	Cut down on the **amount of time** you spent on work or other activities	☐	☐
b.	**Accomplished less** than you would like	☐	☐
c.	Didn't do work or other activities as **carefully** as usual	☐	☐

6 During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(Please mark one box)

- Not at all ☐
- Slightly ☐
- Moderately ☐
- Quite a bit ☐
- Extremely ☐

7 How much **bodily** pain have you had during the **past 4 weeks**?

(Please mark one box)

- None ☐
- Very mild ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Very Severe ☐

8 During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Please mark one box)

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

9 These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks** -

(Please mark one box on each line)

		All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a.	Did you feel full of life?	☐	☐	☐	☐	☐	☐
b.	Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c.	Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d.	Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e.	Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f.	Have you felt down-hearted and low?	☐	☐	☐	☐	☐	☐
g.	Did you feel worn out?	☐	☐	☐	☐	☐	☐
h.	Have you been a happy person?	☐	☐	☐	☐	☐	☐
i.	Did you feel tired?	☐	☐	☐	☐	☐	☐
j.	Has your **health limited your social activities** (like visiting friends and close relatives)?	☐	☐	☐	☐	☐	☐

HEALTH IN GENERAL

10 How **true or false** is **each** of the following statements for you?

(Please mark one box on each line)

		Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a.	I seem to get ill more easily than other people	❑	❑	❑	❑	❑
b.	I am as healthy as anybody I know	❑	❑	❑	❑	❑
c.	I expect my health to get worse	❑	❑	❑	❑	❑
d.	My health is excellent	❑	❑	❑	❑	❑

BRONCHIECTASIS TRIAL

NURSE-LED V DOCTOR-LED OUTPATIENT CARE

CHRONIC RESPIRATORY INDEX QUESTIONNAIRE

Baseline

Patient Study ID Number: | | | |

Date: D D / M M / Y Y Y Y

Survey : 1012

Page : 1

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CHRONIC RESPIRATORY INDEX QUESTIONNAIRE

RESPONSE SHEET

Date of initial interview:

D D M M Y Y

Activities:

Being **angry** or **upset**	1 ☐	**Playing sports**	14 ☐
Having a **bath** or shower	2 ☐	**Reaching** over your head	15 ☐
Bending	3 ☐	**Running,** such as for a bus	16 ☐
Carrying, such as carrying groceries	4 ☐	**Shopping**	17 ☐
Dressing	5 ☐	While trying to **sleep**	18 ☐
Eating	6 ☐	**Talking**	19 ☐
Going for a walk	7 ☐	**Vacuuming**	20 ☐
Doing your **housework**	8 ☐	**Walking** around your home	21 ☐
Hurrying	9 ☐	**Walking** uphill	22 ☐
Making a bed	10 ☐	**Walking** upstairs	23 ☐
Mopping or **scrubbing** the floor	11 ☐	**Walking** with others on level ground	24 ☐
Moving furniture	12 ☐		
Playing with children or Grandchildren	13 ☐	**Preparing** meals	25 ☐

Other Activities

26 ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

27 ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

28 ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

29 ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Activity **3a** ☐☐ **3b** ☐☐

3c ☐☐ **3d** ☐☐ **3e** ☐☐

Survey : 1012

Page : 2

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PAPWORTH HOSPITAL NHS TRUST

CHRONIC RESPIRATORY INDEX QUESTIONNAIRE

Question	Date (D D M M Y Y)
4a	
4b	
4c	
4d	
4e	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	

BRONCHIECTASIS TRIAL

NURSE-LED V DOCTOR-LED OUTPATIENT CARE

THE ST.GEORGES HOSPITAL RESPIRATORY QUESTIONNAIRE

Patient Study ID Number: ☐☐☐

Date: D D / M M / Y Y Y Y ☐☐ / ☐☐ / ☐☐☐☐

Baseline ☐
6 Months ☐
12 Months ☐
18 Months ☐
24 Months ☐

(THE ST. GEORGES HOSPITAL RESPIRATORY QUESTIONNAIRE)

Please use **BLOCK CAPITALS** to enter details clearly or if appropriate mark with a cross like this ☒

PART 1

QUESTIONS ABOUT HOW MUCH CHEST TROUBLE YOU HAVE HAD OVER THE LAST 6 MONTHS.
PLEASE PUT A CROSS, IN ONE BOX FOR EACH QUESTION.

	most days a week	several days a week	a few days a week	only with chest infections	not at all
1. Over the last six months, I have coughed :	☐	☐	☐	☐	☐
2. Over the last six months, I have brought up phlegm (sputum) :	☐	☐	☐	☐	☐
3. Over the last six months, I have had shortness of breath :	☐	☐	☐	☐	☐
4. Over the last six months, I have had attacks of wheezing :	☐	☐	☐	☐	☐

5. During the last six months, how many severe or very unpleasant attacks of chest trouble have you had :

more than 3 attacks ☐

3 attacks ☐

2 attacks ☐

1 attack ☐

no attacks ☐

6. How long did the worst attack of chest trouble last : (Go to Question 7 if you had no severe attacks)

a week or more ☐

3 or more days ☐

1 or 2 days ☐

less than a day ☐

7. Over the last six months, in an average week, how many good days (with little chest trouble) have you had

no good days ☐

1 or 2 good days ☐

3 or 4 good days ☐

nearly every day is good ☐

every day is good ☐

8. If you have a wheeze, is it worst in the morning :

no ☐

yes ☐

(THE ST. GEORGES HOSPITAL RESPIRATORY QUESTIONNAIRE)

SECTION 1 **PART 2**

HOW WOULD YOU DESCRIBE YOUR CHEST CONDITION ? (Please put a cross in one box only)

- the most important problem I have ☐
- causes me quite a lot of problems ☐
- causes me a few problems ☐
- causes no problems ☐

IF YOU HAVE EVER HAD PAID EMPLOYMENT, (Please put a cross in one of these)

- my chest trouble made me stop work ☐
- my chest trouble interferes with my work or made me change my work ☐
- my chest trouble does not affect my work ☐

SECTION 2

QUESTIONS ABOUT WHAT ACTIVITIES USUALLY MAKE YOU FEEL BREATHLESS THESE DAYS
(For each item, please cross either TRUE or FALSE as it applies to you)

	TRUE	FALSE
Sitting or lying still	☐	☐
Getting washed or dressed	☐	☐
Walking around the home	☐	☐
Walking outside on the level	☐	☐
Walking up a flight of stairs	☐	☐
Walking hills	☐	☐
Playing sports or games	☐	☐

SECTION 3

SOME MORE QUESTIONS ABOUT YOUR COUGH AND BREATHLESSNESS THESE DAYS
(For each item, please cross either TRUE or FALSE as it applies to you)

	TRUE	FALSE
My cough hurts	☐	☐
My cough makes me tired	☐	☐
I am breathless when I talk	☐	☐
I am breathless when I bend over	☐	☐
My cough or breathing disturbs my sleep	☐	☐
I get exhausted easily	☐	☐

(THE ST. GEORGES HOSPITAL RESPIRATORY QUESTIONNAIRE)

SECTION 4
QUESTIONS ABOUT OTHER EFFECTS THAT YOUR CHEST TROUBLES MAY HAVE ON YOU THESE DAYS

(For each item, please cross either TRUE or FALSE as it applies to you)	TRUE	FALSE
My cough or breathing is embarrassing in public	☐	☐
My chest trouble is a nuisance to my family, friends or neighbours	☐	☐
I get afraid or panic when I cannot get my breath	☐	☐
I feel that I am not in control of my chest problem	☐	☐
I do not expect my chest to get better	☐	☐
I have become frail or an invalid because of my chest	☐	☐
Exercise is not safe for me	☐	☐
Everything seems too much of an effort	☐	☐

SECTION 5
QUESTIONS ABOUT YOUR MEDICATION. IF YOU ARE RECEIVING NO MEDICATION GO STRAIGHT TO **SECTION 6** (To complete this section, please cross either TRUE or FALSE as it applies to you)

	TRUE	FALSE
My medication does not help me very much	☐	☐
I get embarrassed using medication in public	☐	☐
I have unpleasant side effects from my medication	☐	☐
My medication interferes with my life a lot	☐	☐

SECTION 6
THESE ARE QUESTIONS ABOUT HOW YOUR ACTIVITIES MIGHT BE AFFECTED BY YOUR BREATHING (For each item, please cross either TRUE or FALSE as it applies to you)

	TRUE	FALSE
I take a long time to get washed or dressed	☐	☐
I cannot take a bath or shower, or I take a long time	☐	☐
I walk slower than other people, or I stop for rests	☐	☐
Jobs such as housework take a long time, or I have to stop for rests	☐	☐
If I walk up one flight of stairs, I have to go slowly or stop	☐	☐
If I hurry or walk fast, I have to stop or slow down	☐	☐
My breathing makes it difficult to do things such as walk up hills, carrying things upstairs, light gardening such as weeding, dance, play bowls or golf	☐	☐
My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis or swim	☐	☐
My breathing makes it difficult to do things such as very heavy manual work, run cycle, swim fast or play competitive sports	☐	☐

(THE ST. GEORGES HOSPITAL RESPIRATORY QUESTIONNAIRE)

SECTION 7

WE WOULD LIKE TO KNOW HOW YOUR CHEST TROUBLE USUALLY AFFECTS YOUR DAILY LIFE
(Please cross either TRUE or FALSE as it applies to you because of your chest trouble. remember that TRUE only applies to you if you can not do something **because of your breathing**)

	TRUE	FALSE
I cannot play sports or games	☐	☐
I cannot go out for entertainment or recreation	☐	☐
I cannot go out of the house to do the shopping	☐	☐
I cannot do housework	☐	☐
I cannot move far from my bed or chair	☐	☐

HERE IS A LIST OF OTHER ACTIVITIES THAT YOUR CHEST TROUBLE MAY PREVENT YOU DOING. (**You do not have to cross these**, they are just to remind you of ways in which your breathlessness may affect you)

GOING FOR WALKS OR WALKING YOUR DOG	☐
DOING THINGS AT HOME OR IN THE GARDEN	☐
SEXUAL INTERCOURSE	☐
GOING OUT TO CHURCH, OR PLACE OF ENTERTAINMENT	☐
GOING OUT IN BAD WEATHER OR INTO SMOKY ROOMS	☐
VISITING FAMILY OR FRIENDS OR PLAYING WITH CHILDREN	☐

PLEASE WRITE IN ANY OTHER IMPORTANT ACTIVITIES THAT YOUR CHEST TROUBLE MAY STOP YOU DOING

NOW WOULD YOU CROSS IN THE BOX **(ONLY ONE)** WHICH YOU THINK BEST DESCRIBES HOW YOUR CHEST AFFECTS YOU

It does not stop me doing anything I would like to do	☐
It stops me doing one or two things I would like to do	☐
It stops me doing most things I would like to do	☐
It stops me doing everything I would like to do	☐

THANK YOU FOR FILLING IN THIS QUESTIONNAIRE. BEFORE YOU FINISH WOULD YOU CHECK TO SEE THAT YOU HAVE ANSWERED ALL THE QUESTIONS.

Appendix 4

Patient questionnaire: compliance

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BRONCHIECTASIS TRIAL

NURSE-LED V DOCTOR-LED OUTPATIENT CARE

PATIENT COMPLIANCE QUESTIONNAIRE

Patient Study ID Number: ☐☐☐

Date: D D / M M / Y Y Y Y

Baseline ☐

12 Months ☐

24 Months ☐

Please use **BLOCK CAPITALS** to enter details clearly or if appropriate mark with a cross like this : ☒
Please do not photocopy this form, R&D will issue new forms (contact Vic Lee, ext 4147)

Section A Physiotherapy

1. How many times a day has it been agreed that you should have physiotherapy?

Once a day ☐ Twice a day ☐ More than twice a day ☐

2. Over the last **6 months** which of the following statements best describes you? (cross one box only)

I miss less than one or two days of physiotherapy in 6 months ☐
I miss one or two days of physiotherapy a month ☐
I miss one or two days of physiotherapy a week ☐
I miss more than two days of physiotherapy a week ☐
The only time I do physiotherapy is when I am unwell ☐
I never do my physiotherapy. ☐

3. When I miss my physiotherapy it is because: (cross all that apply)

It interferes with my routine/life/commitments ☐
I don't believe it does any good ☐
It makes me feel worse ☐
I forget ☐
I never miss doing my physiotherapy ☐

Other please comment

4. Do you think the amount of physiotherapy you do is: (cross one box only)

About right ☐ Not enough ☐ Too much ☐ Don't know ☐

Section B Inhalers

5. Are you prescribed preventer inhalers?
(Preventer inhalers are steroid inhalers and include:- Pulmicort, Flixotide, Becotide, Becloforte and Beclazone)

Yes ☐ No ☐

If No go to Section C

6. How many times a day have you been asked to take your preventer inhaler?

7. Over the last **6 months** which of the following statements best describes you? (cross one box only)

- I miss out my preventer inhaler for less than one or two doses in 6 months ☐
- I miss out my preventer inhaler for one or two doses a month ☐
- I miss out my preventer inhaler for one or two doses a week ☐
- I miss out my preventer inhaler for one or two days a week ☐
- I miss out my preventer inhaler for more than two days a week ☐
- The only time I take my preventer inhaler is when I am unwell ☐
- I never take my preventer inhaler ☐

8. When I miss my preventer inhaler it is because: (cross all that apply)

- It interferes with my routine/life/commitments ☐
- I don't believe it does any good ☐
- It makes me feel worse ☐
- I forget ☐
- I never miss taking my preventer inhaler ☐

Other please comment

9. Do you think the amount that you take your preventer inhaler is: (cross one box only)

About right ☐ Not enough ☐ Too much ☐ Don't know ☐

Section C Antibiotics

10. Are you prescribed regular antibiotic therapy (tablets or inhaled)?

Yes ☐ No ☐

If No, then this questionnaire is completed

11. Over the last **6 months** which of the following statements best describes you? (cross one box only)

- I miss less than one or two days of antibiotic therapy in 6 months ☐
- I miss one or two days of antibiotic therapy a month ☐
- I miss one or two days of antibiotic therapy a week ☐
- I miss more than two days of antibiotic therapy a week ☐
- The only time I take the antibiotics is when I am unwell ☐
- I never take the antibiotics ☐

12. When I miss my antibiotics it is because: (cross all that apply)

- It interferes with my routine/life/commitments ☐
- I don't believe it does any good ☐
- It makes me feel worse ☐
- I forget ☐
- I never miss taking my antibiotics ☐

Other please comment

Appendix 5

GP and patient satisfaction questionnaires

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GP satisfaction questionnaire 60
Patient satisfaction questionnaire..... 62

BRONCHIECTASIS TRIAL

NURSE-LED V DOCTOR-LED OUTPATIENT CARE

GP SATISFACTION QUESTIONNAIRE

Patient Study ID Number: ☐☐☐

Date: D D / M M / Y Y Y Y

12 Months ☐

24 Months ☐

PAPWORTH HOSPITAL NHS TRUST

LUNG DEFENCE CLINIC - GP QUESTIONNAIRE

Please use **BLOCK CAPITALS** to enter details clearly, or mark with a cross like this: ☒
Please do not photocopy this form, R&D will issue new forms (contact Vic Lee, ext 4147)

Patient Surname:

Patient Firstname:

Patient date of birth: D D / M M / Y Y Y Y

How many times have you seen this patient in the last 12 months?

How many of these attendances were due to their bronchiectasis?

Did you need to seek direct advice on any occasion? Yes ☐ No ☐

If Yes, how would you rate:

	very good	good	poor	very poor
(a) ease of communication	☐	☐	☐	☐
(b) advice/information received by letter from the Lung Defence Clinic	☐	☐	☐	☐
(c) the care your patient received?	☐	☐	☐	☐

Any other comments

Date form completed: D D / M M / Y Y Y Y

Thank you for your time

Survey : 1017

Page : 2

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BRONCHIECTASIS TRIAL

NURSE-LED V DOCTOR-LED OUTPATIENT CARE

PATIENT SATISFACTION QUESTIONNAIRE

Patient Study ID Number: ☐☐☐

Date: D D / M M / Y Y Y Y

Baseline ☐

12 Months ☐

24 Months ☐

We would like to know how satisfied you are with the care and service you get in the bronchiectasis outpatients clinic.

Could you please help us by completeing this questionnaire by putting a cross in the box which is appropriate to you:

WHAT DO YOU THINK ABOUT THE FOLLOWING

Organisation of the clinic	**Yes, I agree**	**I agree sometimes**	**No, I disagree**	**I can't say**
The waiting area is comfortable	☐	☐	☐	☐
The reception staff are helpful	☐	☐	☐	☐
You are usually seen by the doctor/nurse practitioner within 30 minutes of your appointment time	☐	☐	☐	☐
The general organisation of the clinic is good	☐	☐	☐	☐

Consultation with nurse practitioner / doctor	**Yes, I agree**	**I agree sometimes**	**No, I disagree**	**I can't say**
It is sometimes difficult to discuss your problems with the doctor / nurse practitioner	☐	☐	☐	☐
The doctor / nurse practitioner explains clearly what is wrong	☐	☐	☐	☐
The doctor / nurse practitioner examines you thoroughly when necessary	☐	☐	☐	☐
The doctor / nurse practitioner should tell you more about your illness / condition and treatment	☐	☐	☐	☐
The doctor / nurse practitioner makes you feel at ease	☐	☐	☐	☐
There is not enough time to discuss your problems with the doctor / nurse practitioner	☐	☐	☐	☐
You feel confident the doctor / nurse practitioner knows about your medical history and your care	☐	☐	☐	☐
Sometimes you feel that the doctor / nurse practitioner should listen more to what you say	☐	☐	☐	☐
The doctor / nurse practitioner gives a clear explanation about any tests that you need	☐	☐	☐	☐
You often come away from your appointment wishing you'd asked more questions	☐	☐	☐	☐
You feel you were given a chance to have an active part when discussing your illness / condition	☐	☐	☐	☐
There were frequent interruptions during my consultation	☐	☐	☐	☐

Survey : 1015

Page : 2

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What do you like most about the care you received at the clinic?

What do you like least about the care you received at the clinic?

What do you think could be done to improve the care in this clinic?

Appendix 6

Consultant consultation record

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Consultant Consultation Record

Please use BLOCK CAPITALS to enter details clearly or if appropriate mark with a cross like this: ☒

Study Number:

Attach Patient Addressograph label in this box

Routine visit ☐ Other visit ☐ Date : D D / M M / Y Y Y Y

Discussion **Evaluation by Consultant**

	Acceptable	Unacceptable
Spirometry	☐	☐
Sputum	☐	☐
General	☐	☐

Admitted Yes ☐ No ☐

Medications Changes ☐ No changes ☐

Additional Investigations Yes ☐ No ☐

Specify/ Action

Second Consultant time

Was advice sought: No ☐ During Clinic ☐ During meeting ☐

Amount of medical time required ☐☐ mins

Next review ☐☐ weeks

Prescription Changed Yes ☐ No ☐

Change to:

Comments

Consultant signature _____ Date _____

Survey : 1008 Page : 1

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Appendix 7

Patient diary card

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Additional Comments

DIARY CARD

PROTOCOL NUMBER: PA/005(05)F

Study in Bronchiectasis

Your doctor:

Centre No: **Screening No:**

Patient No: **Patient Initials:**

Date card started: *day* *month* *year*

Date card finished: *day* *month* *year*

PLEASE REMEMBER TO BRING THIS DIARY CARD WITH YOU TO YOUR NEXT CLINIC VISIT

NOTES FOR COMPLETION OF THIS DIARY CARD

Measurement of Peak Flow

1. Always sit down to do your peak flow.
2. Always measure your peak flow at the same time of day.
3. Record the highest peak flow from three separate blows.
4. Perform your peak flow by breathing in as far as you can go, placing the mouthpiece in your mouth and closing your lips tightly around it. Then make a short sharp blow out in to the meter. Record the peak flow value from the scale found opposite the arrow on the grey marker.

Filling in the Diary Card

1. Fill in one column once a week and daily when you having an acute infection.
2. To assess sputum colour, cough some sputum onto a white tissue and compare to the colours shown on the diary card.
3. To record your answer to the questions overleaf choose one number which best describes that particular day.
4. Record details of any new medication you take on page**.
5. If you would like to record any other comments relevant to your participation in this study, please use the comments page at the back of this diary card.

PLEASE LIST ANY NEW MEDICATION TAKEN DURING THESE FOUR WEEKS THAT IS NOT LISTED ON THE SHEET GIVEN BY THE RESPIRATORY NURSE

Date	Drug name and strength	Dose	Reason
EXAMPLE 11/10/97 to 15/10/97	*Paracetamol 500mg*	*2 Tabs*	*Headache*

DIARY CARD

Screening Number: ____

Date *dd/mm/yy*												
Peak Flow (Best of three blows)												
Is your breathing? 0 = Excellent 1 = Good 2 = Normal/Usual 3 = Worse than usual 4 = Bad												
How well do you feel? 0 = Excellent 1 = Good 2 = Normal/Usual 3 = Worse than usual 4 = Bad												
Is your cough? 1 = Persistent 2 = Frequent 3 = Occasional												
Is your sputum? 1 = Watery 2 = Sticky Liquid 3 = Semi-solid 4 = Solid												
What colour is your sputum? Colourless 1 2 3 4 5												
How much sputum do you produce daily? 0 = None 1 = A little (Tablespoonful) 2 = Moderate amount (Egg-cupful or more) 3 = A lot (cupful or more)												
Are you having an acute infection? *Yes/No*												

DIARY CARD

Screening Number: ____

Date *dd/mm/yy*												
Peak Flow (Best of three blows)												
Is your breathing? 0 = Excellent 1 = Good 2 = Normal/Usual 3 = Worse than usual 4 = Bad												
How well do you feel? 0 = Excellent 1 = Good 2 = Normal/Usual 3 = Worse than usual 4 = Bad												
Is your cough? 1 = Persistent 2 = Frequent 3 = Occasional												
Is your sputum? 1 = Watery 2 = Sticky Liquid 3 = Semi-solid 4 = Solid												
What colour is your sputum? Colourless 1 2 3 4 5												
How much sputum do you produce daily? 0 = None 1 = A little (Tablespoonful) 2 = Moderate amount (Egg-cupful or more) 3 = A lot (cupful or more)												
Are you having an acute infection? *Yes/No*												

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Feedback

The HTA Programme and the authors would like to know your views about this report.

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We look forward to hearing from you.

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