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Near patient testing in diabetes clinics: appraising the costs and outcomes

R Grieve
R Beech
J Vincent
J Mazurkiewicz

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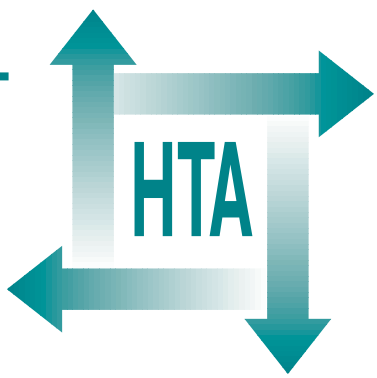
NHS R&D HTA Programme



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Near patient testing in diabetes clinics: appraising the costs and outcomes

R Grieve[1]
R Beech[2]
J Vincent[3]
J Mazurkiewicz[4]

[1] Department of Public Health Sciences, Guy's, King's and St Thomas's School of Medicine, London, UK (corresponding author)
[2] Centre for Health Planning and Management, Keele University, UK
[3] Department of Metabolic Medicine, Guy's Hospital, London, UK
[4] Department of Clinical Chemistry, St Thomas's Hospital, London, UK

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The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

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This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care. It was identified as a priority by the Diagnostics and Imaging Panel and funded as project number 93/06/22.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The editors have tried to ensure the accuracy of this report but cannot accept responsibility for any errors or omissions. They would like to thank the referees for their constructive comments on the draft document.

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The National Coordinating Centre for Health Technology Assessment,
Mailpoint 728, Boldrewood,
University of Southampton,
Southampton, SO16 7PX, UK.
Fax: +44 (0) 1703 595 639 Email: hta@soton.ac.uk
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Contents

List of abbreviations

BMI	body mass index*
CI	confidence interval
CV	coefficient of variation
DCSQ	diabetes clinic satisfaction questionnaire
DTSQ	diabetes treatment satisfaction questionnaire
GGT	gamma-glutamyltransferase
GH	Guy's Hospital*
GP	general practitioner
HbA_{1C}	glycosylated haemoglobin
IDDM	insulin-dependent diabetes mellitus
NIDDM	non-insulin-dependent diabetes mellitus
NPT	near patient testing
RCT	randomised controlled trial
SD	standard deviation
TH	St Thomas's Hospital*

* Used only in tables

Executive summary

Aim

To compare the costs and consequences of providing test results by near patient testing (NPT) compared with conventional testing. The effect of the testing method on the process of care, the accuracy of testing, patient satisfaction, clinical attitudes, and health service and patient costs was investigated. A secondary aim was to generate hypotheses concerning the effect of the testing method on clinical outcome.

Methods and results

Three alternative strategies for analysing and providing test information for patients attending routine diabetes clinics at the Guy's & St Thomas's Hospitals NHS Trust were considered.

1. **Conventional testing**: when a patient attended the clinic the doctor had the option of requesting a test. Results were then sent for processing at a central laboratory with a delay of 5–7 days before requested results were returned. An NPT service for the measurement of glycosylated haemoglobin (HbA_{1C}) existed but was only used for a minority of patients. This represented existing care at Guy's Hospital.
2. **Laboratory NPT**: specialised laboratory personnel operated a testing service next to the diabetes clinic. Test results for blood glucose, HbA_{1C}, lipids and creatinine were available prior to the patient's consultation with the doctor. This represented existing care at St Thomas's Hospital.
3. **Nurse NPT**: samples for testing were analysed by a nurse using desktop analysers in the clinic. The results of tests requested by doctors were available prior to the patient's consultation. This scheme was piloted at Guy's Hospital over a 3-month period.

Process of care

A controlled trial compared the effect of the testing method on the process of care. A total of 599 patients were alternately allocated to either nurse NPT or conventional testing. The number of management changes to the patients' diet, insulin or tablet therapy was recorded for all the patients. The results showed that patients were more likely to have a change in management related to their glycaemic control if they had been in the NPT rather than the conventional testing group (odds ratio 1.52; 95% confidence interval (CI) 1.02–2.26). Subgroup analysis showed that patients with poor glycaemic control were more likely to have management changes in the NPT than in the conventional group (odds ratio 1.75; 95% CI 1.12–2.76). For patients with good control the number of management changes did not differ according to the testing method employed (odds ratio 0.92, 95% CI 0.35–2.44). This suggested that the process of care may be improved if results related to glycaemic control (HbA_{1C}) are provided by NPT.

There did not seem to be any improvement in the process of care from providing lipid or creatinine results immediately, which suggests that the merits of NPT are likely to vary according to the test in question.

Accuracy of test results

NPT in general maintained acceptable standards of quality control.

Patient satisfaction and patient knowledge

Self-administered patient questionnaires were used to assess levels of patient satisfaction with the alternative strategies. Patients for both NPT strategies were significantly more satisfied with the test information provided, than those who were conventionally tested (laboratory NPT versus conventional, $p = 0.004$; nurse NPT versus conventional, $p < 0.001$).

A higher proportion of users of the NPT services recalled being told the result of their HbA_{1C} test (64%) compared with those who used the conventional testing service (19%). For a minority of patients in the conventional group, HbA_{1C} results were provided immediately.

Clinical attitudes

A sample of doctors interviewed stated that immediate access to HbA_{1C} results meant that they could make more informed decisions about what changes in management should be implemented. They also said that without immediate access to

test results, changes in patient management might be sub-optimal.

Conventional testing was considered adequate for lipids and creatinine results. Some clinicians were concerned that NPT may lead to organisational delays in the diabetes clinic.

Clinical outcome

A retrospective cohort study compared intermediate clinical outcome, measured by mean HbA_{1C}, between patients using conventional ($n = 500$) and laboratory NPT ($n = 500$) strategies. This aspect of the study aimed to generate further hypotheses concerning the effect of testing method on clinical outcome. After controlling for case-mix variables, mean HbA_{1C} was significantly lower for the NPT cohort compared with the conventional testing cohort. The potential for confounding in the design of the study means that a prospective randomised controlled trial (RCT) is required to investigate further the effects of NPT on patient outcome.

Health service costs

The number of tests and the use of staff time was measured for a sample of patients tested by each method. The costs of conventional testing were then compared with both NPT strategies. Mean visit costs were £3.80 higher for laboratory NPT and £12.60 higher for nurse NPT than for conventional testing, reflecting the greater number of tests conducted at NPT visits and the higher capital equipment costs of NPT. However, sensitivity analysis showed that the additional costs fell if NPT was used just for HbA_{1C} tests. In this study, the mean difference in annual costs between the two approaches was not significant as the mean number of visits per year was lower for laboratory NPT.

Patient costs

Patient questionnaires were used to measure the patient costs associated with each method. Patient time per visit did not vary according to the testing method used. Users of the laboratory NPT service made fewer visits to the diabetes clinic (1.81 per annum) compared with users of the conventional testing clinic (2.28 per annum). This meant that in the settings examined, annual patient costs were higher for conventional testing than for NPT.

Frequency of patient visits

Health service and patient costs are affected by the impact of NPT on the frequency of patient visits to clinics. In this study, users of an established NPT service made fewer hospital visits per annum than those of a conventional service. However, it is not possible to say that these differences were a direct result of NPT or due to other differences in clinical practices and the organisation of care between the two hospital sites.

Other results from this study support a hypothesis that there may be a direct link between NPT and the frequency with which patients need to attend hospital clinics. Generally, under conventional testing, results which were not immediately available were not mailed to either the patient or their general practitioner. The users of the test information were thus hospital doctors and the next available time that the information could be used to support a management change was during the patient's next hospital appointment. This method of transmitting and using test information may mean that under conventional care patients need to be called to the clinic more frequently.

A prospective RCT is needed to firmly establish the link between NPT and the frequency of patient visits to clinics.

Future research

The results of this initial research project indicate that providing HbA_{1C} results by NPT seems to improve the process of care and aspects of patient satisfaction. A prospective RCT of NPT in diabetes clinics is now needed. The aims of this trial should be to establish:

- the impact of NPT on clinical outcomes
- the impact of NPT on the frequency of patient visits to clinics
- the impact of any changes in the above on health service and patient costs.

Chapter 1

Near patient testing in diabetes clinics: project overview

Background

A recent advance in medical technology has been the development of near patient testing (NPT). Under this system a sample of, for example, blood or urine is rapidly analysed near to the location where the patient is receiving care. The doctor is then able to discuss the results of the test with the patient immediately and implement any required changes in management. NPT moves elements of pathology and other diagnostic services away from centralised laboratories. Settings for NPT can include hospital wards, outpatient clinics and general practice surgeries.

When this project began, a range of applications and equipment for NPT had been described in the scientific literature.[1–3] These included: desktop blood analysers for the measurement of glucose, cholesterol, uric acid, sodium and potassium, aspartate aminotransferase, alanine aminotransferase, gamma-glutamyltransferase (GGT) and creatinine kinase; and 'dipstick' urine tests for the diagnosis of urinary tract infection, pregnancy, vaginal infections and sexually transmitted diseases. In the USA, widespread use of NPT had been reported. Stoeckle[4] estimated that about 20% of medical practitioners had their own office laboratory, and Hailey and Lea[1] that 79% of physician's offices had some form of NPT biochemistry equipment. In the UK the growth of NPT had been more limited. Hilton[2] argued that the capital costs of NPT equipment may have limited its use in general practice. In the hospital setting, Marks[3] suggested that the potential benefits of NPT meant the devolution of laboratory services to settings such as intensive care units, operating theatres, inpatient wards and outpatient departments should be considered as part of a strategy for developing pathology services.

However, although NPT had become increasingly available and the trend was towards increased use, evidence of its effectiveness and cost-effectiveness was limited. The potential benefits hypothesised in the literature included:

- an improvement in clinical outcome because more immediate feedback of test results allows any required changes in patient management to be implemented more quickly
- an improvement in patient satisfaction and a reduction in patient costs because patients get their test results more quickly and the number of clinical visits per patient is reduced.

Among the potential drawbacks of NPT suggested were:

- its costs to the health service relative to conventional testing
- a reduction in the accuracy of test information because quality control standards can be maintained less easily when testing is not at a central laboratory.

However, the general conclusion of the authors of these papers was that more research was needed before definite decisions about the effectiveness and cost-effectiveness of NPT could be made.[1–3]

One of the main evaluations of the costs and consequences of NPT to be conducted in the UK was that by Rink and Hilton.[5] They assessed the impact of introducing NPT in the general practice setting for the measurement of cholesterol, haemoglobin, GGT, electrolytes, midstream urine and chlamydia. The study covered 12 practices with list sizes of over 9000 from both inner-London and rural settings, and compared the utilisation of tests before and after the introduction of NPT.

The availability of test equipment increased the overall number of tests requested per patient by 16.5%. When the equipment was removed the utilisation of tests returned to the baseline level, the implication being that the increased usage was caused by the availability of NPT. In general, this increase was in addition to any tests requested from centralised laboratories. Only for midstream urine tests was NPT substituted for conventional testing.

With the exception of midstream urine, average costs per test were higher for NPT. Taking NPT for cholesterol as an example, Rink and Hilton[5] estimated that the increased requests for tests coupled with the higher unit costs would cause the annual

costs of cholesterol testing to rise by about £3260 per practice.

The availability of NPT equipment caused a significant reduction in the number of investigations and referrals for urinary tract infections and an improvement in the recording of patient data about cardiovascular risk factors. This suggested that NPT could lead to improvements in the process of care. However, the overall conclusion was that NPT in general practice was only likely to be cost-effective for midstream urine analysis.

Hence, although when this report was commissioned various claims had been made about the potential merits of NPT, there was very little evidence about its effectiveness and cost-effectiveness.

The main study[5] to be conducted in the UK suggested that NPT was generally not cost-effective compared with laboratory testing.

However, the difficulty with attempting to make generalisable statements about NPT is that cost-effectiveness is likely to vary according to the disease group and the test in question. This likely variability is reflected in the design of this study which focuses on the effects of introducing NPT for certain test results for patients with diabetes. The importance of evaluating NPT for this particular patient group and the choice of study design are explained below.

Evaluating the costs and outcomes of NPT in diabetes clinics

Rationale for the project

Diabetes mellitus is a chronic condition with a population prevalence of between 1% and 2%, and the care of people with diabetes consumes about 4–5% of the total NHS budget.[6]

The monitoring of blood glucose control is a particularly important aspect of diabetes care since the achievement of good control in patients with insulin-dependent diabetes mellitus (IDDM) reduces the risk of long-term diabetes complications.[7] This finding may also be applicable to patients with non-insulin-dependent diabetes mellitus (NIDDM).[8] Monitoring can be based on home testing or on random blood glucose measurement but the effectiveness of solely relying on these techniques has been questioned.[9] Improved glycaemic control can be achieved by the regular monitoring of glycosylated haemoglobin (HbA_{1C}).[10] This test accurately measures blood glucose control within the previous 4 months.[11]

There are a number of ways in which NPT might contribute to the care of patients with diabetes. NPT means that an HbA_{1C} test result could be available immediately in a diabetes clinic. The result, and any planned changes in management, could then be discussed with the patient. By contrast, with conventional testing, in which results are sent away to a central laboratory, any changes in diabetes management may be delayed. The delays could affect the flow of communication between doctor and patient, as well as the patient's understanding of information received.

NPT may also affect patient and clinical outcomes. Improved levels of satisfaction may result from the changes in the organisation and delivery of the processes for analysing and providing test information. These changes may also mean that the patient achieves better glycaemic control than with conventional testing.

NPT may affect patient costs by reducing the number of contacts that patients have with healthcare professionals, either because of a more efficient system for testing and providing test information, or because of any improvements in clinical outcome. These changes would reduce the magnitude of patient costs both in terms of financial and time inputs. For a chronic condition such as diabetes, patients have to make regular visits to healthcare providers, so reductions in patient costs are important.

These effects are all potential gains from NPT. However, as indicated by Rink and Hilton,[5] an adverse consequence of NPT is that it may increase healthcare costs.

Research strategy

Although a range of effects of NPT could be hypothesised, existing research indicated that its main effects would be on the process (in terms of timing and utilisation of testing) and costs of care. Concern had also been expressed about its impact on the accuracy of testing.

The objectives and design of this project reflected these previous research findings, which had also guided decisions about the appropriate duration and costs of this project.

Given the overall lack of evidence about the effectiveness and cost-effectiveness of NPT, a broad perspective was taken and the effect of

NPT on a number of indicators was considered; for example, the impact of NPT on patient and clinical outcomes was investigated.

This broad perspective meant that, in addition to generating important information about the consequences and costs of NPT, another role of the project was to generate hypotheses to be explored in future research.

Aims of the study

The overall aim of the study was to assess the impact of NPT on the consequences and costs of care. To achieve this aim the project team investigated:

(i) the impact of NPT on the process of care and the accuracy of testing
(ii) the impact of NPT on patient satisfaction
(iii) the views of health service professionals on the different approaches to testing
(iv) the possible impact of NPT on clinical outcome, measured by the difference in mean HbA_{1C}, between patients tested in conventional and NPT clinics
(v) the health service costs of providing each testing service
(vi) the patient costs associated with each approach.

Objectives (i), (v) and (vi) reflect previous research findings about NPT. In addition, information about test accuracy and process of care are important for generating hypotheses about why a given testing strategy may affect patient and clinical outcomes. These effects were explored through objectives (ii) and (iv). HbA_{1C} was the direct marker of clinical outcome used in the study. The views of healthcare professionals (objective (iii)) will affect the rate of adoption of a healthcare technology. The information collected can also be used to help interpret why a testing strategy may affect clinical and patient outcomes.

Research setting and the testing strategies evaluated

The study compared existing services for routine diabetes outpatient care within the Guy's & St Thomas's Hospitals NHS Trust in inner London (the hospitals are about 1 mile apart). Both are large general acute teaching hospitals serving populations with a broad range of socio-economic and ethnic backgrounds. The existing service arrangements examined were as follows.

- ***Conventional testing as practised at Guy's Hospital*** When a patient attended a clinic the doctor had the option of requesting a test, the result of which was sent for processing at a central laboratory. There was a delay of 5–7 days before requested results were returned. A limited NPT service for the measurement of HbA_{1C} also existed but was used only for a minority of patients.
- ***Laboratory NPT as practised at St Thomas's Hospital*** Specialised laboratory personnel operated a laboratory next to the diabetes clinic. Test results for blood glucose, HbA_{1C}, lipids and creatinine were available before a patient's consultation with the doctor. This represented existing care at St Thomas's Hospital.

In addition to existing service arrangements, the following approach to NPT was piloted and evaluated.

- **Nurse NPT** This was introduced at Guy's Hospital, samples for testing being analysed by a nurse using desktop analysers. Again, the results of the tests were available before a patient's consultation.

Overview of research methods

The breadth of the issues addressed by this study meant that a range of methodological approaches were employed – prospective and retrospective, quantitative and qualitative. For each aspect, subsequent chapters of this report describe in detail the methods used, the data collected, the results obtained and their implications. However, it is helpful to outline here the reasons for the choice of methodology for examining the clinical impacts of NPT and the anticipated role of any findings in guiding future healthcare policy and research.

Issues surrounding the design of the study of clinical outcomes

One methodology for examining the impact of NPT on clinical outcomes would have been a prospective randomised controlled trial (RCT) covering all three testing strategies. Such a design was considered but was rejected. Instead, the study of clinical outcomes was based on a retrospective study covering patients who had been treated using conventional and laboratory NPT strategies at the Guy's and St Thomas's Hospitals, respectively. The reasons for this choice of study design were as follows.

- The clinical outcome in question, HbA_{1C} level, has a long latency period. Hence, measuring this effect in a prospective study would have had substantial implications for both the duration and costs of the overall study. Given that the

available literature suggested that the study of clinical outcome was a speculative component of the project, such implications were not thought to be justified until more evidence had been generated to support the hypothesis that NPT affects clinical outcome. A retrospective study was therefore seen as an appropriate stepping-stone to any prospective controlled study.

- The choice of research methodology had three important implications for the results of this aspect of the study:
  (i) the clinical outcomes achieved by the nurse NPT strategy were not measured directly; instead the outcomes achieved by the laboratory NPT strategy were taken as a proxy for those that might be achieved by the nurse NPT strategy
  (ii) the study design chosen controlled for differences in case-mix between the two hospitals but did not control for additional confounding factors which may have led to differences in clinical outcomes between patients treated at the two hospitals, such as the availability of other technologies, the experience of the doctors and the clinical protocols at the two sites
  (iii) the existence of additional confounding factors which were not controlled for meant that any results generated by the retrospective study would have to be confirmed by a prospective RCT; the role of the results of the retrospective study would be to generate the rationale (or lack of rationale) for such a trial and the hypothesis to be tested.

Structure of the report

For each aspect of the study, the methods used, the data collected, the results obtained and their implications are described in detail in subsequent chapters.

The impact of NPT is considered in relation to:

- test accuracy and the process of care (chapter 2)
- patient satisfaction (chapter 3)
- professional views (chapter 4)
- clinical outcome (chapter 5)
- health service costs (chapter 6)
- patient costs (chapter 7).

In the final chapter of the report, the broader implications of the study's findings are discussed, together with the conclusions that can be drawn regarding the merits of NPT and the areas in which more research is needed.

Summary

- Under NPT a test sample is rapidly analysed at the patient-care setting.
- Previous research suggested that, in general, NPT increased costs and led to changes in the utilisation of testing.
- NPT has the potential to improve the process of care for patients with diabetes.
- The aim of the study was to measure the impact of adopting this technology according to a broad range of indicators covering the consequences and costs of care.
- It was accepted at the outset of the project that, in addition to generating important information on the consequences and costs of NPT, some results would be used to postulate hypotheses for future research, particularly in relation to the impact of NPT on clinical outcomes.

Chapter 2

The feasibility of introducing an NPT system and the effect of NPT on the process of care

Introduction

As part of the study, nurse NPT was introduced at Guy's Hospital between 4 June and 30 September 1996. This part of the study explored the feasibility of introducing nurse NPT in a diabetes clinic with a throughput of about 48 patients per clinic. This was an important aspect of the study since consideration was given to whether there were any reasons why the costs and consequences of nurse NPT might differ from laboratory NPT. The principal endpoints were the proportion of results that were processed successfully and the extent to which quality control standards were maintained. Recent guidelines for the introduction of NPT[12] have emphasised the importance of maintaining internal quality control standards.

This aspect of the study also evaluated whether the immediate transmission of test results changed the management of the patients' diabetes. This study was designed to provide information regarding the process of care that could explain why NPT may effect clinical outcome. A controlled trial compared the impact of the different testing methods on the process of care.

Methods

Feasibility of introducing nurse NPT

Every patient who attended the routine diabetes clinic during this period had a sample of blood analysed using NPT equipment. HbA_{1C} results were processed using two Bayer DCA 2000™ analysers. The results were available in 9 minutes. Glucose, cholesterol and creatinine results were processed using two Biomen Spotchem® machines. The testing system was operated by a research nurse, two care assistants, a phlebotomist and an unqualified laboratory technician.

The nurses operating the equipment had a 3-hour training session with a laboratory technician from each equipment manufacturer. In addition, supervision regarding the use of the equipment and quality control was provided by a senior biochemist from the central laboratory.

Internal quality control was performed by the research nurse using material from the commercial manufacturer. The material was reconstituted, aliquoted and frozen, and then thawed and analysed at each clinic session. The results were monitored by a qualified laboratory technician from the central laboratory.

The mean, standard deviation (SD) and coefficient of variation (CV) were calculated for each test and the results compared with those obtained at the central laboratory, where established quality control standards were used.

Trial measuring the effect of NPT on the process of care

Trial protocol

The aim was to evaluate the effect of NPT on the number of management changes for patients allocated to NPT or conventional testing. Patients were included in the controlled trial who attended the follow-up clinic between 4 June and 30 September 1996. No patients were excluded from the trial. On arrival at the clinic patients were alternatively assigned into Groups A and B (*Figure 1*). Thus the trial may be described as a controlled trial rather than an RCT. No previous studies had evaluated the number of management changes for patients with diabetes. Thus, making a prospective power calculation was difficult since it required knowledge of the expected mean number of changes for each group. The length of the trial period was instead determined by the time available within the research project (4 months) rather than by a power calculation.*

For patients in Group A, the doctor had full test information available before the consultation. Group B acted as a control group, with only blood glucose results made immediately available. Other test results were available, if requested, a few days

* The significance of this for the study results are discussed later.

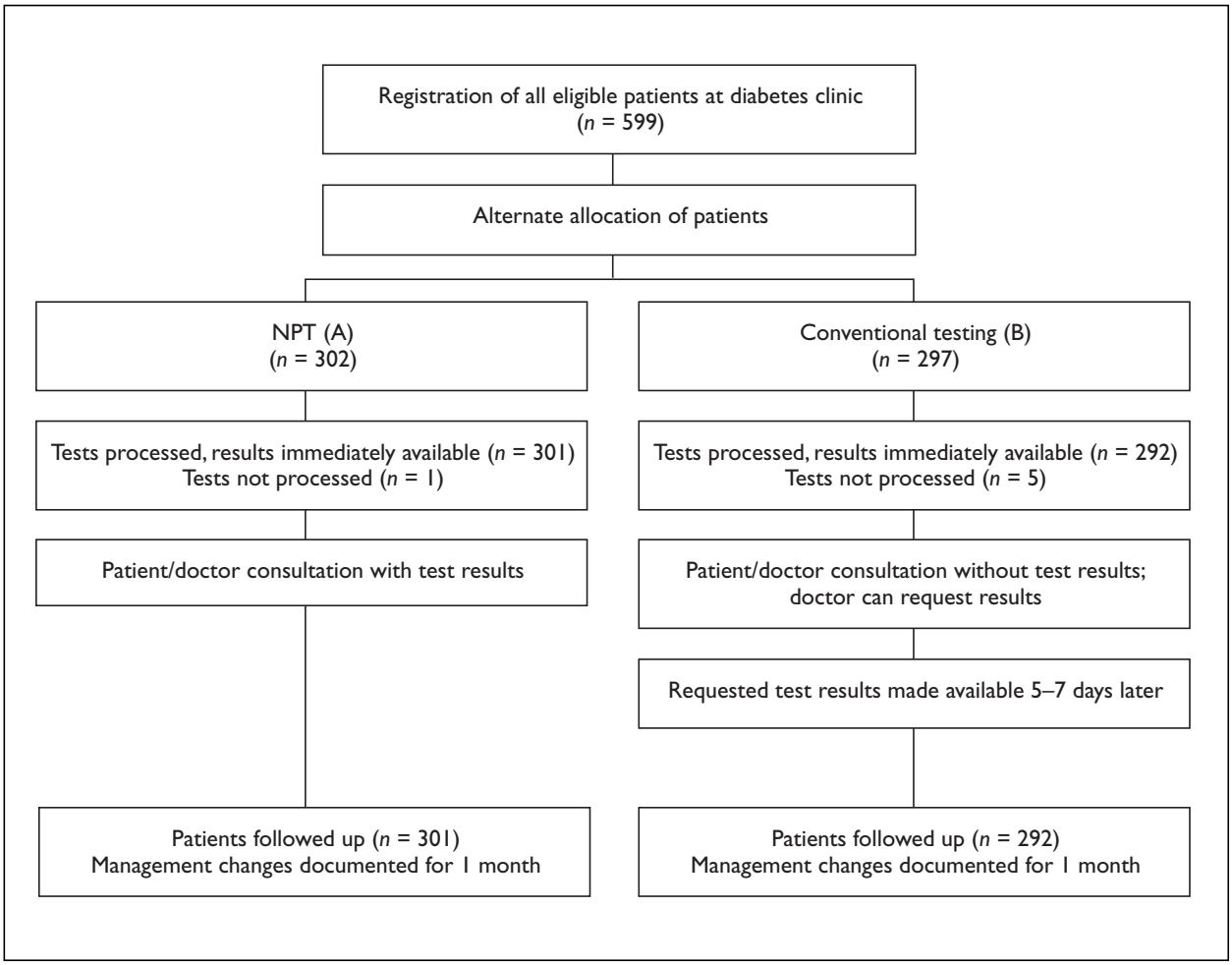

FIGURE 1 *Design of controlled trial comparing NPT with conventional testing*

later. Thus the procedure for patients in group B replicated conventional testing. All test results were recorded and used to describe the baseline characteristics of the two groups.

Following a visit to the routine diabetes clinic, a hospital doctor writes to the patient's general practitioner (GP) and explains whether any management changes or additional visits are required by the patient (see appendix 1). From these letters, changes in the process of care were recorded. These changes were categorised according to the aspect of the patient's management to which they related. The letters were monitored for up to 1 month after the appointment concerned. This period of follow-up was based upon the expected maximum time that would elapse between a patient attending clinic and a clinician writing to the patient's GP about the outcome of the visit.

Assignment of patients

Patients were allocated to Groups A or B according to whether the number of a ticket given to a patient upon arrival at the clinic was odd or even. The tickets were handed out by administration staff at the clinic. The identities of the two groups were concealed from the staff allocating the patients.

After being tested, patients had to wait before seeing the doctor. This meant that they did not undertake the intervention in the order in which they were assigned into Group A or Group B. Thus, although the allocation to the two groups was systematic, the intervention was not administered according to a systematic ordering.

Statistical methods

Mantel–Haenszel and Miettinen tests were used to calculate the relevant odds ratios and 95% confidence intervals (CIs).

Results

Feasibility study

During the study period, 599 patients attended the routine diabetes clinic. Test results were

processed for 593 patients; six test results were not processed or were lost.

The quality control results for both normal and abnormal samples for the NPT equipment are shown below (*Tables 1* and *2*). For abnormal samples, CV was less than 6% for all tests. The internal quality control for these samples compared favourably with the standard maintained at the central laboratory (*Tables 3* and *4*).

For normal samples, the quality control for NPT samples was comparable to central laboratory testing for HbA_{1C}, lipids and glucose. However, for creatinine samples measured on the Spotchem machines, CV values were very high (CV_1 = 17.5; CV_2 = 14.9).

Process measures

Management changes relating to glycaemic control

Of the 599 patients included in the trial, 302 were assigned to NPT (Group A) and 297 to conventional testing (Group B). The allocation of patients between the groups resulted in an even distribution of baseline characteristics (*Table 5*). For six patients (one patient in Group A and five in Group B), the equipment failed to analyse their samples.

The effect of the availability of test information on the number of management changes relating to glycaemic control is shown in *Table 6*. The patients in each group were subdivided into those whose glycaemic control was good or poor. This was because the number of management changes

TABLE 1 *Internal quality control for NPT: within run imprecision for normal samples analysed by NPT equipment*

Test	**HbA_{1C}**		**Cholesterol**		**Triglyceride**		**Glucose**		**Creatinine**	
Equipment	**DCA analyser**		**Spotchem**		**Spotchem**		**Spotchem**		**Spotchem**	
Machine number	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**
n	33	33	29	29	29	29	34	32	36	34
Mean	5.63	5.46	3.45	3.47	0.58	0.58	2.15	2.25	44.1	51.1
SD	0.19	0.18	0.14	0.13	0.03	0.03	0.17	0.11	7.7	7.6
CV (%)	**3.3**	**4.4**	**4.1**	**3.7**	**5.2**	**5.2**	**7.9**	**4.9**	**17.5**	**14.9**

TABLE 2 *Internal quality control for NPT: within run imprecision for abnormal samples analysed by NPT equipment*

Test	**HbA_{1C}**		**Cholesterol**		**Triglyceride**		**Glucose**		**Creatinine**	
Equipment	**DCA analyser**		**Spotchem**		**Spotchem**		**Spotchem**		**Spotchem**	
Machine number	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**
n	33	33	28	30	29	30	32	32	35	26
Mean	12.1	11.7	6.02	6.00	1.7	1.69	14.4	14.0	707	721
SD	0.53	0.55	0.14	0.15	0.06	0.06	0.5	0.51	31.9	36.9
CV (%)	**4.4**	**4.7**	**2.4**	**2.5**	**3.4**	**3.3**	**3.5**	**3.6**	**4.5**	**5.1**

TABLE 3 *Internal quality control for NPT: within run imprecision for normal samples analysed at the central laboratory*

Test	**HbA_{1C}**	**Cholesterol**	**Triglyceride**	**Glucose**	**Creatinine**
Mean (SD)	4.85 (0.18)	3.3 (0.15)	0.78 (0.10)	4.1 (0.10)	71.5 (3.25)
CV (%)	3.6	4.5	6.4	2.4	4.5

TABLE 4 *Internal quality control for NPT: within run imprecision for abnormal samples analysed at the central laboratory*

Test	**HbA_{1C}**	**Cholesterol**	**Triglyceride**	**Glucose**	**Creatinine**
Mean (SD)	9.4 (0.20)	6.1 (0.25)	2.01 (0.14)	14.7 (0.35)	697 (18.2)
CV (%)	2.1	4.1	7.0	2.4	2.6

TABLE 5 *Characteristics of patients allocated to NPT or conventional testing: values are* n *(%) unless stated otherwise*

Characteristic		Nurse NPT (Group A)	Conventional testing (Group B)
Number		302	297
Women		139 (46)	129 (43)
Age, years: mean (SD)		59.7 (13)	59.4 (14)
Treatment:	diet	30 (10)	31 (10)
	tablet	166 (55)	153 (52)
	insulin	106 (35)	113 (38)
Retinopathy		84 (28)	91 (31)
Neuropathy		110 (36)	114 (38)
HbA_{1C}: mean (SD)		8.43 (1.6)	8.57 (1.6)

may be associated with a patient's health status and the method of providing test information.

For those patients with good glycaemic control, the distribution of the number of management changes was similar in both groups. The odds ratio for this subgroup of patients was 0.918. This indicates that for patients with good glycaemic control there was a reduced chance of a management change if the results were provided by NPT. However, the reduced chance of being prescribed a management change is not statistically significant (95% CI, 0.35–2.44).

For patients in both groups whose glycaemic control was poor, more changes in management were prescribed. However, there were 23 additional management changes for patients in Group A (NPT) compared with Group B (conventional testing). The odds ratio for this intervention was 1.75. This means that the patients with poor glycaemic control were more likely to have a change in management if NPT was used than if they were conventionally tested. This finding was statistically significant (95% CI, 1.12–2.72).

The combined odds ratio for all the patients was 1.52 (95% CI, 1.02–2.26). For all patients there was a significantly higher probability of them being prescribed a change in management if they were in Group A rather than in Group B.

Management changes relating to cholesterol, triglycerides and creatinine

Patients were more than twice as likely to have a change in cholesterol management if they were in Group A (odds ratio 2.32, 95% CI, 1.46–8.55). However, a total of only 23 patients over the 3-month period had any change in management related to cholesterol testing (*Table 7*). This suggests there is only a small potential benefit from providing this information by NPT.

There was little evidence of management changes being made for patients in either group from information regarding triglyceride and creatinine levels.

Effect of the provision of test information on referrals to other healthcare settings

The effect of the provision of test information on the referrals made by the doctors is shown in *Table 8*. Of the patients referred to the specialist nurse, 60% were from Group B – which may have been because the doctors wanted to see these

TABLE 7 *The effect of the availability of test information on the number of management changes relating to cholesterol levels*

Testing strategy	Change in management		Total
	Yes	No	
NPT (A)	16	286	302
Conventional (B)	7	290	297
Total	23	576	599

TABLE 6 *The effect of the availability of test information on management changes relating to glycaemic control*

Glycaemic control	Testing strategy	Management change, proportion (%)	Odds ratio (95% CI)
Good control (HbA_{1C} < 7.5%)	NPT (A)	9/94 (10)	0.92 (0.35–2.44)
	Conventional (B)	9/87 (10)	
Poor control (HbA_{1C} > 7.5%)	NPT (A)	67/207 (32)	1.75 (1.12–2.72)
	Conventional (B)	44/205 (21)	
Total	NPT (A)	76/301 (25)	1.52 (1.02–2.26)
	Conventional (B)	53/292 (18)	

TABLE 8 *The effect of the availability of test information on referrals from the diabetes clinic*

Testing strategy	Referred to:				Not referred	Total
	Day ward/ specialist nurse	Dietician	Lipid clinic	Other		
NPT (Group A)	25	21	1	1	254	302
Conventional (Group B)	37	16	0	1	243	297
Total	62	37	1	2	497	599

patients to discuss their test results at a later date. This has implications for the costs incurred by the system. However, a higher proportion of the referrals to a dietician (60%) were from patients in Group A, which may reflect a closer monitoring of cholesterol results for patients in this group.

Discussion

The results suggest that it is possible to provide an NPT service in a routine diabetes clinic for 599 patients over a 12-week period. For 99% of patients, results were available prior to their consultation with the doctor. The introduction of nurse NPT generally did not cause quality control standards to slip below the level acceptable to the central laboratory. The only result which demonstrated poor between-run precision was creatinine for normal control. This finding demonstrates the importance of monitoring quality control when introducing an NPT service.

The results from the controlled trial suggest that providing immediate test results for HbA_{1C} leads to significantly more management changes being made. The subgroup analysis reveals that these additional changes were made for patients whose glycaemic control may be regarded as poor.

The immediate provision of cholesterol results only appeared to effect a very small group of patients. No evidence was found to suggest management changes using triglyceride and creatinine results were affected by the method of test provision.

However, before this evidence is used to suggest that the introduction of NPT leads to an improved clinical outcome, certain questions must be answered.

To what extent does any improvement in the process of care necessarily lead to an improvement in outcome?

The results of this aspect of the study do not address the question of whether or not the increase in the number of management changes associated with NPT necessarily lead to an improvement in clinical outcome. To establish whether the patients in the intervention group would experience an improvement in their glycaemic control, it would be necessary to follow up both patient groups over a longer period. This is an area which the authors are currently investigating. Such a study would also need to compare the costs of treating the two patient groups.

Could the observed increase in the number of management changes made for patients in the NPT group be attributed to selection bias?

Research has shown that non-randomised studies yielded larger estimates of treatment effects than studies using random allocation.[13] A recent study suggested that the main reason for this observed effect is inadequate concealment of allocation to the treatment and the control group.[14] The authors of this study suggest that:

> "Bias even appears to arise in trials labelled as 'randomised' if investigators fail to prevent foreknowledge of treatment allocation."

Using a randomised method in accordance with recent guidelines[15] requires using a randomisation procedure followed by concealment of randomisation using serially numbered opaque envelopes. This method of randomisation was not adopted because the researchers were concerned about the disruption that this would cause to the clinic. It was considered likely that randomisation would make it more difficult to assess the feasibility of operating a nurse NPT system in a routine diabetes clinic – the first objective of this study. Given these concerns, patients were assigned to groups according to whether or not they had been given an odd or even ticket on arrival at the clinic.

However, since the evidence suggests that the concealment of allocation is the most important criteria for minimising bias in an RCT, the most pertinent question to ask relating to study design is:

Did the study fail to minimise bias because the allocation of patients was inadequately concealed?

The outlined allocation procedure meant that staff allocating patients were unaware of the identity of the two groups. They would not, therefore, have been able to change the allocation process. Both doctors and patients were unaware of the intervention assigned until the time of intervention. At this point it was impossible to reverse the allocation.

Were the additional management changes associated with NPT a sign of intervention bias?

Since it was impossible to blind the doctors involved in the study, there was the potential for intervention bias. However, this seems unlikely for two reasons: first, for HbA_{1C} results the incremental change in management for patients in Group A was for those whose glycaemic control was poor. This suggests that these patients had a capacity to benefit which the doctors did not have the information to recognise for similar patients in Group B. If more changes had been made for patients in Group A compared with Group B irrespective of need, then there would have been stronger evidence of intervention bias. Second, the reluctance of doctors to enact management changes for Group A patients on the basis of the other results provided suggests that the doctors were not making management changes simply to demonstrate an improvement in the process of care from the provision of test results by NPT.

Was the length of follow-up sufficient?

One month was chosen for the length of follow-up; this allowed sufficient time for the doctor to make any changes in management following the return of results requested for Group B. In fact, no changes were made to patients' management following the initial letters to their GPs which were sent before the test results had been received. This illustrates the problems of having the relevant information delayed under the conventional testing approach.

No prospective power calculation was done for this study: did this mean the study was underpowered?

A prospective power calculation was not undertaken because the information required to make this calculation was not available. In particular, the mean numbers of management changes for patients in each group were not available from the literature. Instead the study duration was set by the confines of the research period at 3 months. The problem of using this method is that it could have meant that the sample size was inadequate to test the null hypothesis and lead to the null hypothesis being falsely accepted: a type II error. Plenty of coverage has been given in clinical outcomes literature to the problem of type II errors (see, for example, Campbell, *et al.,* 1996[16]). In this study, a type II error would have occurred had the null hypothesis (that the number of changes does not differ between groups) been accepted because of inadequate sample size rather than because the effect did not exist.

For the given sample who completed the trial (301 patients in Group A, 292 in Group B), the power calculation was performed with the acceptable probability of type I errors (incorrectly rejecting the null hypothesis) and type II errors (incorrectly accepting the null hypothesis) set at 5% and 10%, respectively. The power calculation was then performed for the main measurement of effect in the study – the mean difference in management changes relating to glycaemic control. It was calculated that this sample size could detect a mean difference between the two groups by the proportion who had a management change of 7%. A difference of less than 7% would not have been found to be significant. The principle result of the study was that the overall difference in the proportion of patients who had a management change in response to an HbA_{1C} result was 7% and this difference was found to be statistically significant. Hence, for this test result, the chosen sample size was adequate to find the difference in the proportion tested statistically significant. Thus, although the power calculation was not performed in advance, it does not appear to have affected the main conclusion, viz. that the number of management changes relating to glycaemic control varied according to the method of test provision.

Conclusion

Nurse NPT was introduced for 599 patients over a 3-month period during which an acceptable standard of quality control was maintained. A controlled trial demonstrated that NPT led to more management changes for patients who have poor control. Under conventional testing, doctors did not appear to change patient management following the receipt of test information. This suggests that information relating to control is not delivered at the optimal time by a conventional testing system. Thus, NPT for HbA_{1C} may be said to improve the process of care. However, whether this leads to an improvement in clinical outcome is more debatable and is an issue that will be further examined and debated in subsequent chapters.

Summary

- Nurse NPT was a feasible way of providing test information in a hospital diabetes clinic.
- A controlled trial design was used to measure the effect of NPT on the process of care.
- Patients were more likely to have a change in management relating to an HbA_{1C} result if they had NPT rather than conventional testing.
- Most patients who had management changes had poor control.
- NPT for lipids and creatinine did not effect the process of care.
- Quality control standards for nurse NPT were adequate.

Chapter 3

Patient satisfaction and patient knowledge

Introduction

In this section of the study, the hypothesis that the provision of test results by NPT may lead to an improved level of patient satisfaction and patient awareness of test results is considered.

Patient satisfaction may vary according to clinical outcome and the importance of patient satisfaction measures in studies evaluating blood glucose control has been demonstrated.[17] It may be that the introduction of NPT encourages a doctor to change a patient's treatment regime. Even if this means an improvement in glycaemic control, the patient may be less satisfied with their treatment. Alternatively, the introduction of NPT may mean that patients' consider that their treatment is more appropriate to them. This could be because they feel their consultation with the doctor has been on the basis of full information.

Patient knowledge has been shown to be an important determinant of outcome for diabetes patients;[18] therefore, in this part of the study, the facets of patient knowledge which were considered likely to vary according to the testing regime employed were monitored.

Method

Selection and development of study instruments

In order to address the different areas of patient satisfaction and knowledge, patient questionnaires developed from three sources were used.

1. A diabetes treatment satisfaction questionnaire (DTSQ) was used to see whether patients' satisfaction with their treatment for diabetes differed according to the method of providing test information. The version used in this study has proved highly reliable with good construct validity, sensitivity to change and discriminatory power for patients with IDDM and NIDDM.[19] The scale has been shown to be useful in clinical trials evaluating new technologies.[20] The DTSQ uses a visual analogue scale to elicit patients' views on different aspects of their satisfaction with their treatment regimes. It consists of eight questions (see appendix 2 (page 57, questions 28–35)). The scores from questions 28, 31, 32, 33, 34, and 35 are summed to give a total score for treatment satisfaction which can range from 0 (very dissatisfied) to 36 (very satisfied). In addition to looking at treatment satisfaction, the questionnaire considers the patients' perception of diabetes outcome as measured by their perceived frequency of hypo- and hyperglycaemic attacks. These are measured on a scale ranging from 0 (none of the time) to 5 (most of the time).
2. The second measure used was an amended version of the diabetes clinic satisfaction questionnaire (DCSQ).[19] Patients were asked to circle a number to reflect their level of satisfaction with different aspects of the diabetes clinic. These items were summed to give a total score ranging from 0 (very dissatisfied) to 45 (very satisfied) (see appendix 2 (page 55, questions 15–25)).
3. A supplementary questionnaire was developed by the authors of this study to measure other pertinent items of patient satisfaction not considered in the other questionnaires and to monitor the relevant aspects of patient knowledge. The questions focused on whether patients were aware of whether they had received test results relating to their blood glucose control and cholesterol levels (see appendix 2 (page 53, questions 7–10, 13, 14, 26 and 27)).

Distribution of questionnaires

The first batch of questionnaires (see appendix 2, pages 52–58) were used to compare satisfaction under the conventional testing regime at Guy's Hospital with laboratory NPT at St Thomas's Hospital. Conventional testing at Guy's Hospital comprised central laboratory testing and NPT for a minority of patients. Excluding patients from the NPT sub-sample could have led to selection bias, so they were included. The DTSQ was handed out to 516 consecutive patients who attended the respective diabetes clinics in February and March 1996. The DCSQ and the patient knowledge and satisfaction questionnaires were given to 831 consecutive patients who attended either clinic between January and March 1996.

The second batch of questionnaires (see appendix 2, pages 59–62) were distributed to 404 consecutive patients who attended the diabetes clinic at Guy's Hospital between July and September 1996 when nurse NPT was introduced. These questionnaires were a truncated version of the earlier versions and monitored more specific aspects of patient satisfaction directly related to the provision of test information.

Although all the patients in this sample were tested using NPT, only those assigned to Group A had instant feedback of test results. Results for patients in Group B were not made available until several days later. Patients' satisfaction with test information in Group A was compared with that in Group B.

The questionnaires were completed by the patients themselves. When patients were unable to answer the questions, their relatives were asked to complete the questionnaires on their behalf.

Non-parametric tests were used to detect whether there were significant differences between the various groups of patients sampled.

Results

Comparison between conventional testing (Guy's Hospital) and laboratory NPT (St Thomas's Hospital)

DTSQ

A total of 322 patients (62%) agreed to complete the DTSQ. The mean HbA_{1C} for the patients who agreed to participate (8.23%) was similar to those who refused (8.25%). The results from the questionnaire are shown below (*Table 9*).

The sample of patients at Guy's Hospital recorded a slightly higher median total treatment satisfaction score than those at St Thomas's Hospital. This difference was not statistically significant ($p = 0.09$). The patients who attended the NPT clinic had a higher perceived frequency of hyperglycaemia than their counterparts at Guy's Hospital ($p = 0.005$).

DCSQ

In all, 595 patients (73%) agreed to complete the questionnaire on clinic satisfaction and patient awareness. The difference in metabolic control between participants ($HbA_{1C} = 8.08$) and non-participants ($HbA_{1C} = 8.28$) was not statistically significant ($p = 0.227$).

The findings (see *Table 10*) suggest that patients at both hospitals were very satisfied with the service provided by the clinic. Patients at the NPT clinic were slightly more satisfied (median = 41) than patients in the conventional testing clinic (median = 40). This difference in the total clinic satisfaction scores was not statistically significant, neither were most of the individual scores for clinic satisfaction. However, there were two individual parameters which did show a statistically significant difference between the two clinics. These were satisfaction with the test information given by the staff ($p = 0.004$), and satisfaction with the way in which a patient was treated by staff ($p = 0.04$).

The highly significant result for satisfaction with test information cannot be explained by considering just the median and upper and lower percentiles. Instead, it is necessary to consider the frequency distribution of the two different samples shown in *Figure 2*. This illustrates that over 75% of patients in the NPT clinic recorded a satisfaction level with test information of at least 4, compared with 60% for conventional testing.

Patient knowledge

A similar number of patients recalled having a random blood glucose taken at the last diabetes clinic (91.5% at Guy's Hospital compared with 95.8% at St Thomas's Hospital). However, the number of patients who confirmed they had an HbA_{1C} sample taken at the last clinic was much lower under conventional testing than for NPT (*Table 11*).

The relative frequency of each method of conveying the results is shown in *Table 12*. A significantly greater proportion of patients at St Thomas's Hospital (NPT: 71%) were aware they had been

TABLE 9 *Treatment satisfaction in patients attending a clinic using conventional testing compared with those who attended a clinic using NPT*

	Conventional testing (GH) median (range)	NPT (TH) median (range)	*p*-value
Satisfaction with treatment (range 0–30)	27 (5–30)	26 (14–30)	0.09
Perceived frequency of hyperglycaemia (range 0–5)	2 (0–5)	3 (0–5)	0.005
Perceived frequency of hypoglycaemia (range 0–5)	1 (0–5)	1 (1–5)	0.162

TABLE 10 *Treatment satisfaction in patients attending a clinic using conventional testing compared with those who attended a clinic using NPT*

Measure	Conventional (GH)			Laboratory NPT (TH)			*p*-value
	10%	median	90%	10%	median	90%	
Total clinic satisfaction (0–45)	27	40	45	30	41	45	0.54
Time with doctor (0–5)	3	5	5	3	5	5	0.97
Advice from doctor (0–5)	3	5	5	4	5	5	0.96
Continuity of care (0–5)	2	5	5	2	5	5	0.83
Problems with doctor (0–5)	3	5	5	3	5	5	0.70
Extent to which feel understood by doctor (0–5)	3	5	5	3	5	5	0.49
Information given by staff (0–5)	3	5	5	3	5	5	0.004
How treated as a person by staff (0–5)	3	5	5	4	5	5	0.04
Waiting time (0–5)	2	4	5	2	4	5	0.81
Overall satisfaction with clinic (0–5)	3	5	5	3	5	5	0.43

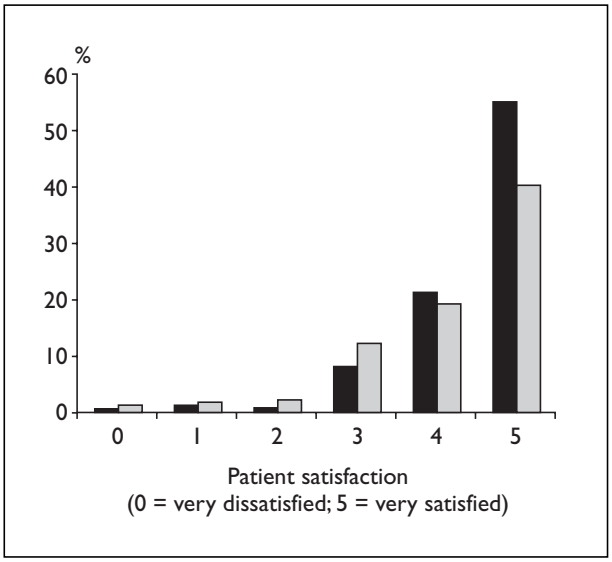

FIGURE 2 *Patient satisfaction with test information following laboratory NPT ■ compared with conventional testing □ (NB: 12% of NPT patients and 22% of conventional testing patients did not respond)*

tested for HbA_{1C} than at Guy's Hospital (conventional: 41%) ($p = 0.001$).

At Guy's Hospital 54 patients (19% of overall sample) reported being told of an HbA_{1C} measurement at the same clinic as they took the test; this reflected the move to introduce NPT for some patients. However, 20 patients (16.2%) at Guys' Hospital said they had never received the result and 17 said they had been required to wait until the next clinic.

TABLE 11 *The patient's perception of whether they were tested for HbA_{1C}*

Were you tested for HbA_{1C} at last diabetes clinic?	Conventional (GH) *n* (%)	Laboratory NPT (TH) *n* (%)
Yes	118 (41.4)	218 (70.8)
No	80 (28.0)	26 (8.4)
Don't know	59 (20.7)	45 (14.6)
Missing	28 (9.8)	19 (6.2)
Total	**285**	**308**
p = *0.001*		

TABLE 12 *The communication of the test result for HbA_{1C}*

Were you tested for HbA_{1C}, how were you told the result of test?	Conventional (GH) *n* (%)	Laboratory NPT (TH) *n* (%)
Same clinic	54 (46.0)	190 (87.2)
Next clinic	17 (14.4)	5 (2.3)
Extra clinic	2 (1.7)	1 (0)
By post	3 (2.5)	3 (1.4)
Didn't get result	20 (16.9)	5 (2.3)
Other	9 (7.6)	0 (0)
Missing	13 (11.0)	14 (6.4)
Total	**118**	**218**

TABLE 13 *Possible reasons why patients feel immediate feedback of an HbA_{1C} test result is important for the management of their diabetes*

(i) An immediate feedback of the HbA_{1C} results is important to me as it allows me to discuss my results with the doctor at the clinic

Location	Disagree strongly	Disagree	Neutral	Agree	Agree strongly	Missing	Total
GH	0	0	2 (3.7)	16 (29.6)	32 (59.2)	4 (7.4)	54
TH	0	0	1 (0.5)	47 (24.7)	131 (68.9)	11 (5.8)	190

(ii) Knowing my HbA_{1C} level helps me to understand my diabetes

	Disagree strongly	Disagree	Neutral	Agree	Agree strongly	Missing	Total
GH	0	1 (1.8)	1 (1.8)	20 (37.0)	28 (51.8)	4 (7.4)	54
TH	0	2 (1.0)	8 (4.2)	54 (28.4)	114 (60.0)	12 (6.3)	190

TABLE 14 *Comparison of patient satisfaction with waiting times at Guy's Hospital before and after the introduction of nurse NPT*

How satisfied were you with the time spent waiting at the diabetes clinic?

Testing method	0 (very dissatisfied)	1	2	3	4	5 (very satisfied)	Missing	Total
Conventional	5 (1.7)	17 (6.0)	33 (11.6)	56 (19.6)	47 (16.5)	79 (27.7)	48 (16.8)	285
Nurse NPT	8 (2.8)	6 (2.3)	18 (6.4)	52 (18.6)	52 (18.5)	129 (46.1)	15 (5.3)	280

p = *0.038*

At St Thomas's Hospital, 190 patients recalled being tested for HbA_{1C} at the same clinic as they took the test.

Of the 244 patients at both clinics who had received immediate HbA_{1C} results, 93.6% felt having this result at the same clinic was important. The reasons for this are explored in *Table 13*.

At both hospitals there was strong agreement between patients that the immediate feedback of HbA_{1C} is important because it allows patients to discuss their results with the doctor at the clinic. A majority of patients at both hospitals also considered that the immediate feedback of HbA_{1C} results helped them to understand their diabetes.

The introduction of nurse NPT

In all 280 patients (69%) agreed to participate in the study. The mean control did not differ significantly ($p = 0.30$) between those who agreed ($HbA_{1C} = 8.56$) and those who refused ($HbA_{1C} = 8.42$) to participate. The patients' satisfaction with waiting time during the period of NPT was significantly higher than it had been during conventional testing ($p = 0.038$) (see *Table 14*).

The difference in satisfaction with test information between Group A and Group B is shown in *Figure 3*. The results show that patients who received an immediate feedback of information were significantly more satisfied than those who were tested conventionally ($p < 0.001$).

The earlier finding that patients who had NPT were more likely to have their HbA_{1C} result communicated to them than if they were conventionally tested was also found to apply to cholesterol. Of the patients in Group A, 30% recalled being tested for cholesterol and being told the result straight away compared with those in Group B, for whom the corresponding figure was 9%.

Discussion

The first comparison of patient satisfaction showed that neither treatment satisfaction nor clinic satisfaction differed significantly between conventional testing (Guy's Hospital) and NPT (St Thomas's

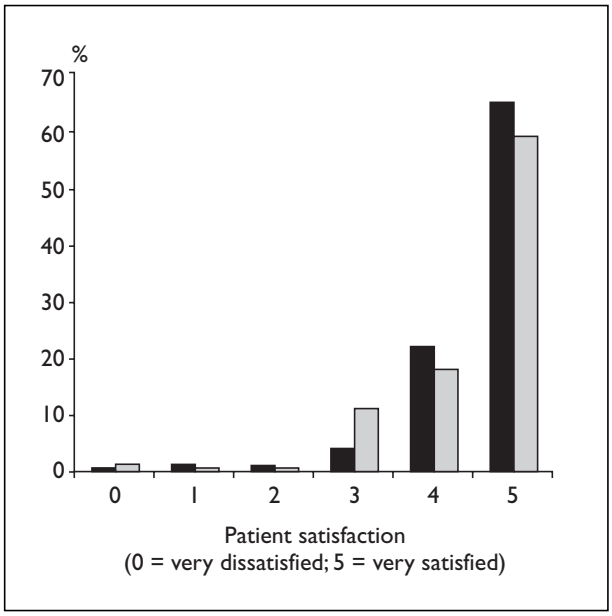

FIGURE 3 *Patient satisfaction with test information with nurse NPT(A) ■ compared with conventional testing (B) □ (NB: 4% of NPT patients and 1.5% of conventional testing patients did not respond)*

Hospital). The patients receiving NPT were significantly more satisfied with their test information although they had a higher perceived frequency of hypoglycaemia.

The finding that the treatment satisfaction did not appear to differ between the two hospitals is important. It could have been the case that even if the introduction of NPT did improve control it led to a reduction in treatment satisfaction. Hence, it was important that the study monitored any possible adverse effects of the introduction of NPT on patient satisfaction.

Patients in the NPT sample having a higher perceived frequency of hypoglycaemia would seem to contradict any hypothesis that NPT leads to improved blood glucose control (chapter 5). However, in a previous study,[21] it was found that if patients are given information regarding their diabetes control, they are likely to base their perceptions of their own blood glucose control on this objective evidence, whereas those with little evidence will base their views on general feelings. This would seem to apply to these results; the perceived frequency of hypoglycaemia seems to increase with patient's awareness of their blood glucose control.

The result most directly applicable to the study question is that the patients are more satisfied with test information if it is available immediately. This result from the first comparison between St Thomas's and Guy's Hospitals was confirmed by the comparison between the satisfaction levels of patients in Groups A and B at Guy's Hospital during the nurse NPT trial. The results of the trial also suggested that the satisfaction of patients with test information can improve soon after the introduction of an NPT system.

The results from the comparison of satisfaction with waiting time before and after the introduction of NPT at Guy's Hospital suggested that patients were more satisfied with waiting time following the introduction of NPT. The conclusion cannot be definitely reached that improved satisfaction with waiting time was the direct result of the introduction of NPT since it was not possible to use the same patients in each sample, and there may have been other changes during the interim period. In addition, the existence of the nurse NPT study may have led to a 'Hawthorne' effect among patients. However, the finding does suggest that when the introduction of this system is carefully planned, it need not necessarily cause dissatisfaction with waiting time.

The results from the patient awareness section of the questionnaires showed that patients were more likely to recall being tested for HbA_{1C} if this test result had been processed by NPT. This reflects the more regular monitoring of HbA_{1C} under NPT and the increased likelihood of the doctor communicating the result to the patient. For the patients who were given results for HbA_{1C} immediately, there was a consensus that these results were important.

Under conventional testing, even if the patient did recall being tested for HbA_{1C}, they were less likely to be told the result. The difference in patient awareness would have been larger if the conventional testing location had not started to introduce NPT for some patients prior to the survey.

The results from the trial suggest that cholesterol results provided by NPT are more likely to be communicated to patients than for conventional testing. However, it appears that cholesterol results were communicated to patients less frequently than HbA_{1C} results. Thus, there appears to be less benefit to the patient from having this result immediately available.

Conclusion

The introduction of NPT for HbA_{1C} improves the likelihood of glycaemic control being monitored and discussed with the patient. The patient seems to regard this as important and is more satisfied with the test information provided.

Summary

- Patients' satisfaction with their diabetes clinic and treatment was evaluated for each of the three strategies.
- Treatment satisfaction and overall clinic satisfaction did not differ between approaches.
- Patients reported a higher frequency of hypoglycaemia in the NPT group.
- Patients were more satisfied with test information if they had NPT rather than conventional testing.
- In all, 62% of patients at St Thomas's Hospital and 19% of patients at Guy's Hospital recalled being told the result of HbA_{1C} testing at the same clinic as they took the test. This reflects the recent introduction at Guy's Hospital of an NPT system for a minority of patients.
- Patients were more likely to be given their HbA_{1C} result if they had NPT; they regarded the result as important.
- Patient/doctor dialogue could be improved under NPT, which may help patients to achieve better diabetes control.

Chapter 4

Clinical attitudes to NPT

Introduction

Clinical attitudes surrounding the merits of a technology are key factors surrounding its adoption.[22] If the perceived merits of a technology are low this will impede implementation. The piloting of nurse NPT at Guy's Hospital represented an ideal opportunity to compare the views of clinicians about the piloted strategy and the existing conventional strategy.

Methods

Following the period during which nurse NPT had been introduced, semi-structured interviews were conducted with ten doctors at Guy's Hospital. The sample represented all doctors who had undertaken two or more outpatient diabetes clinic sessions during the period of piloting. All the doctors had worked in the clinic prior to the piloting of NPT and the purpose of the interviews was to obtain their views on the possible advantages and disadvantages of providing an NPT service.

The semi-structured format allowed respondents to raise areas of concern to them but each doctor was asked the following questions.

- What do you consider to be the main advantages of the NPT system compared with a conventional system in which results are not available for several days?
- Do you consider it helps in:
  (a) decisions regarding the patient's management?
  (b) the patient's education?
  (c) the ease of communication of the patient's needs both for the patient and their GP?
- Are there any potential drawbacks of having such a system?
- Would you prefer to see a continuation of the [NPT] system in the trial in which the results are instantly available for HbA_{1C}, creatinine, triglycerides and cholesterol, or do you consider it is only important to have HbA_{1C} results instantly available?
- Are there any other results whose instant availability you consider necessary?

The interviews were transcribed and analysed, the aim being to highlight key themes surrounding the advantages and disadvantages of NPT.

Results

Nine of the ten doctors interviewed emphasised the advantages of having an HbA_{1C} result immediately available. The following quotes illustrate the views expressed.

> "NPT is essential for HbA_{1C}; without this result available the doctor is practically blind." (Doctor 2)

> "The biggest advantage of an NPT service for diabetes clinics is in having a HbA_{1C} [result] immediately available." (Doctor 7)

When asked specifically why they felt that NPT for HbA_{1C} was preferable to conventional care, the doctors explained how it helped to improve clinical decision making:

> "...having an HbA_{1C} [result] immediately enables the doctor to make a rational and informed decision regarding the patient's management of their diabetes." (Doctor 4)

> "HbA_{1C} is important, it helps you to achieve the fundamental objective of good control." (Doctor 2)

Others suggested that having an HbA_{1C} result immediately available made them more confident about decisions they were already taking at the diabetes clinic. The doctors referred to the importance of being able to compare other information presented to them, such as random blood glucose and patients' self monitoring, to HbA_{1C}. They felt this allowed a precise summary measure of patients' blood glucose control over the previous 3 months.

> "[having an HbA_{1C} by NPT is a] big advantage for your own management of the patient, you know exactly what's going on and can compare it with what the patient's saying to you." (Doctor 2)

The following quote probably best illustrates the way in which NPT can affect both the direction and timing of clinical decision making:

> "...if you see an HbA_{1C} [result] of 8.5 when the patient is in the clinic you are quite likely to take action to try to get it down to 7.5. If, however, you see the patient a week later you are unlikely to take action. You accept control is not optimal but you let it go." (Doctor 8)

The above findings indicate that doctors think the immediate availability of an HbA_{1C} result has an important role in improving clinical decision making. Doctors also indicated that immediate access to HbA_{1C} test results improved the organisational efficiency of the service for both doctors and patients. Six out of ten doctors indicated that they would not have to call patients back to the clinic so frequently, and four out of ten the improved ease of getting test results to the GP. Under conventional testing the doctors cited the problems of the results getting lost.

> "If I have the results immediately available I can make a management decision at the time. It saves on an extra visit and means a better management decision for the patient." (Doctor 9)

> "Requesting an HbA_{1C} is totally inconvenient. You might assume that a patient's control is reasonable but then receive a high HbA_{1C} [result]. Should you then recall the patient or spend time writing to the GP?" (Doctor 10)

Finally, six out of ten doctors indicated that the immediate availability of an HbA_{1C} result helped with patient education and led to an improved meeting between doctor and patient. Other doctors (three out of ten) said that it enabled them to give immediate feedback to every patient, whether positive or negative, that related to the management of their diabetes.

> "People feel that their clinic visit every 6 months has been of some benefit."(Doctor 5)

> "I feel more able to respond to patients' needs and questions." (Doctor 3)

When asked about the advantages and disadvantages of having cholesterol, triglycerides and creatinine results instantly available the doctors were less positive. They generally seemed to regard these results as 'useful' and 'helpful', if they were provided in this manner rather than 'very important' or 'essential' as was the case for HbA_{1C}. Given the choice, even if results for lipids and creatinine were immediately available, the doctors considered it to be unnecessary to have all patients screened at every clinic.

> "Although it is useful to have the cholesterol result available there and then, you do not need to have the cholesterol every time you see the patients; I would recommend measuring it once a year or for those in need of treatment." (Doctor 8)

One doctor suggested that conventional testing was adequate for these results and this summarised a generally held belief among the doctors that there appeared to be no incremental benefit from having these results provided immediately.

These views emphasise the dangers of making generalised statements about the merits of NPT. Its relevance depends upon the nature of the disease being treated and, within disease groupings, the nature of the test being requested.

Most of the doctors concerned did not cite any organisational disadvantages from an NPT system. Two mentioned problems with the delays associated with an NPT system. However, this could have resulted from initial problems during the piloting of the nurse NPT system. In practice, these initial difficulties in the organisation of the system were resolved.

Conclusion

The clinicians in this sample had positive attitudes to the introduction of NPT for HbA_{1C}, considering that it had benefits for both doctors and patients. Clinical resistance would not therefore appear to be a major obstacle to the implementation of this technology. Importantly, doctors believed that NPT improved both the quality of clinical management and the nature of clinical decisions. Under conventional testing they indicated that changes in management may be sub-optimal and/or delayed.

Summary

- Doctors were interviewed to find out what they regarded as the advantages and disadvantages of NPT.
- In general, doctors considered that having access to an immediate HbA_{1C} result was important because it meant they could make an informed decision regarding a patient's diabetic management.
- Some doctors said that under conventional testing they may have to request an extra clinic visit for the patient.
- Doctors considered that conventional testing was adequate for lipids and creatinine results, indicating that the merits of NPT will vary according to the test being requested (and the disease being treated).
- Some clinicians were concerned that NPT might lead to organisational delays in the diabetes clinic.

Chapter 5

Intermediate clinical outcome

Introduction

Previous results from this project indicate that NPT may lead to an improvement in glycaemic control in diabetes patients. This is further explored here. A retrospective cohort study compared the mean HbA_{1C} for patients tested in a conventional manner at Guy's Hospital with those tested under laboratory NPT at St Thomas's Hospital. The limitations of the study design and the reasons for its adoption were outlined in chapter 1. The purpose of this aspect of the study was not to establish whether or not a definite link existed between NPT and improved clinical outcome but to generate further evidence to assess whether or not there might be a relationship. This, and other evidence generated by the study, would then be used to assess whether or not a prospective randomised trial was justified to confirm, or not, the relationship between NPT and improved clinical outcome.

Patients and methods

Patients who attended the routine diabetes clinic at the Guy's and St Thomas's Hospitals between October 1995 and March 1996 were considered for inclusion in the study. This period was chosen because it allowed the research team access to the medical records of the subjects selected. A total of 1591 patients were initially selected, 768 at Guy's Hospital and 823 at St Thomas's Hospital.

Patients were excluded from the main analysis if data were not available on the last three HbA_{1C} results or for baseline characteristics, because of the requirement to control for any differences in the baseline characteristics of the populations.

For the patients who met the above criteria, a sample of 500 was included from each hospital. For both hospitals the patients selected were those who had most recently attended the diabetes clinic.

Data collection was from patient records at Guy's Hospital and from Diabeta, the computerised patient database, at St Thomas's Hospital. The last three HbA_{1C} results were recorded in order to calculate the mean level for each patient, correcting for measurement differences between the two methods of measuring HbA_{1C}. Data on age, sex, date of diagnosis, treatment type, body mass index, occupation and ethnic background were recorded. These were all factors which prior to the investigation were regarded as possible predictors for the level of HbA_{1C}. Patients were classified into social classes 1–5 from the standard classification index,[23] using the subject's own occupation. If a patient did not state an occupation, a proxy for social class was used where possible. For example, for a married woman the husband's occupation was taken to represent her social class.

Statistical analysis

Linear regression analysis was used to identify factors influencing HbA_{1C} results for patients attending the two clinics. Results are presented as least-squares means (with 95% CIs).

Results

The results from the unadjusted linear regression analysis on all patients considered for inclusion in the model are shown in *Table 15*. The mean HbA_{1C} level is significantly higher for the patient sample at Guy's Hospital than at St Thomas's Hospital. For both groups the level of control is higher than the targets suggested by recent guidelines where a level of HbA_{1C} greater than 7.5% was defined as representing poor control.[24*]

This shows that for the patients included in the initial sample, the mean HbA_{1C} result for the sample who attended the conventional testing clinic was significantly higher.

The population characteristics of the patients included in the main analysis are described in *Table 16*. The population distribution of the two

[*] Absolute values have largely been replaced as targets since they depend on the reference range for the particular assay used. Thus, the above target can only be regarded as an approximate guideline for what might constitute poor control.

TABLE 15 *Unadjusted linear regression looking at the relationship between HbA_{1C} level and hospital for patients who met the inclusion criteria*

Hospital (number of patients)	Mean HbA_{1C} level (%)	Standard error	95% CI (lower)	95% CI (upper)
GH (768)	8.66	0.056	8.55	8.77
TH (823)	7.79	0.058	7.67	7.90
$p < 0.001$				

TABLE 16 *Demographic characteristics of 1000 diabetes patients attending routine clinics at Guy's and St Thomas's hospitals (values are* n *(%) unless stated otherwise)*

Demographic characteristics		Conventional testing (GH) (n = 500)		Laboratory NPT (TH) (n = 500)	
Gender	Male	291	(58.2)	266	(53.2)
	Female	209	(41.8)	234	(46.8)
Treatment	Diet	28	(5.6)	36	(7.2)
	Tablet	281	(56.2)	183	(36.6)
	Insulin	191	(38.2)	281	(56.2)
Age	Mean (SD)	59.3	(13.1)	54.8	(15.8)
Social class*	1–2	104	(20.8)	125	(25.0)
	3–5	345	(69.0)	205	(41.0)
	9	51	(10.2)	170	(34.0)
Ethnic group	Caucasian	369	(73.8)	336	(67.2)
	Afro-Caribbean	84	(16.8)	122	(24.4)
	Asian	38	(7.6)	32	(6.4)
	Other	9	(2.0)	10	(2.0)
Duration of diabetes	Mean (SD)	11.5	(9.7)	14.1	(9.3)
BMI	Mean (SD)	28.8	(5.9)	28.0	(5.0)

* *For a subsample of patients, social class was not classifiable from the information given, e.g. patients who had retired but did not give a previous occupation. Rather than excluding them from the analysis, such patients were allocated a separate social class (9)*

patient groups was broadly similar. However, the comparison between the two hospitals does reveal that, at Guy's Hospital, the patients were more likely to be men, of a lower social class and on oral hypoglycaemic therapy.

The unadjusted linear regression analysis presented in *Table 17* shows that before controlling for other factors, the hospital visited has a statistically significant effect on the mean level of HbA_{1C} ($p < 0.001$). However, this effect may be confounded by the observed differences in case-mix. The other variables considered each had an effect on HbA_{1C} results which was statistically significant. The treatment type ($p < 0.001$) and the patient's social class ($p < 0.001$) also had highly significant effects on the level of HbA_{1C} control. It was therefore important to control for possible differences in the distribution of all these variables between the two hospitals.

Any differences between the two groups in terms of the population characteristics outlined were controlled for using multiple linear regression anaysis. The level of glycaemic control measured by the percentage of HbA_{1C} was taken as the independent variable. The most suitable model (*Table 18*) was chosen using a backward stepwise approach. Each of the least-squares means are adjusted for the effect of each of the other variables. The effect of hospital on HbA_{1C} control is shown to be statistically significant ($p < 0.001$), controlling for all listed confounders.

Discussion

The evidence from this cohort study suggests that, after controlling for differences in case-mix, diabetes patients who attended a clinic with a

TABLE 17 *Associations of explanatory variables with HbA_{1C} (n = 1000)*

Characteristic		Mean HbA_{1C}	Standard error	Lower CI	Upper CI
Hospital	GH (conventional)	8.83	0.070	8.69	8.97
	TH (NPT)	8.40	0.070	8.26	8.54
		$p < 0.001$			
Ethnic background	Caucasian	8.49	0.057	8.38	8.60
	Afro-Caribbean	8.96	0.105	8.75	9.17
	Asian	8.81	0.180	8.46	9.16
	Other	8.69	0.345	8.01	9.37
		$p < 0.001$			
Age group (years)	< 35	8.07	0.151	7.77	8.37
	35–44	8.67	0.145	8.37	8.97
	45–54	8.74	0.126	8.49	8.99
	55–64	8.65	0.085	8.48	8.82
	> 64	8.67	0.083	8.51	8.83
		$p < 0.001$			
Gender	Female	8.49	0.064	8.36	8.62
	Male	8.77	0.071	8.63	8.91
		$p < 0.001$			
Treatment	Diet	7.36	0.190	6.99	7.73
	Tablet	8.85	0.076	8.70	9.00
	Insulin	8.60	0.062	8.48	8.72
		$p < 0.001$			
Social class*	1, 2	8.78	0.064	8.65	8.91
	3, 4, 5	8.51	0.105	8.30	8.72
	9	8.33	0.100	8.13	8.53
		$p < 0.001$			
Years diagnosed	< 5	8.99	0.103	8.79	9.19
	5–10	8.56	0.081	8.40	8.72
	11–20	8.53	0.137	8.26	8.80
	21–29	8.57	0.200	8.18	8.96
	> 30	8.43	0.093	8.25	8.61
		$p < 0.001$			
BMI	< 20	8.88	0.315	8.26	9.49
	20–25	8.40	0.100	8.20	8.60
	25–30	8.56	0.074	8.41	8.71
	> 30	8.84	0.095	8.65	9.03
		$p = 0.005$			

* *For a subsample of patients, social class was not classifiable from the information given, e.g. patients who had retired but did not give a previous occupation. Rather than excluding them from the analysis, such patients were allocated a separate social class (9)*

laboratory NPT system achieved better glycaemic control than those who attended a diabetes clinic where test results were processed by conventional testing. However, before any definite conclusions can be drawn, certain questions need to be asked about this result.

Is the observed difference in effectiveness clinically significant?

The issue of what change in level of HbA_{1C} may be regarded as clinically significant is largely subjective. One recent study described a fall in the level of glycaemic control of 0.7% as 'clinically relevant'.[26] Another study suggested that taking into account all types of analytic variation meant that only changes in HbA_{1C} levels greater than 0.65% could be regarded as clinically significant.[27] However, the study was considering a clinically significant change for an individual patient. In this evaluation, whether the intervention concerned made a clinically significant difference was assessed

TABLE 18 *Multiple linear regression model for HbA_{1C} in 1000 patients attending Guy's and St Thomas's Hospitals*

Characteristic		Mean HbA_{1C}	Standard error	Lower CI	Upper CI
Hospital	TH	8.26	0.144	7.98	8.54
	GH	8.61	0.156	8.30	8.92
		$p < 0.001$			
Ethnic background	Caucasian	8.19	0.110	7.97	8.41
	Afro-Caribbean	8.58	0.148	8.29	8.87
	Asian	8.59	0.202	8.19	8.99
	Other	8.39	0.347	7.71	9.07
		$p = 0.004$			
Age group (years)	< 35	8.14	0.202	7.74	8.54
	35–44	8.60	0.191	8.23	8.97
	45–54	8.57	0.180	8.22	8.92
	55–64	8.37	0.152	8.07	8.67
	> 64	8.51	0.154	8.21	8.81
		$p = 0.09$			
Gender	Female	8.55	0.149	8.26	8.84
	Male	8.33	0.149	8.04	8.62
		$p = 0.02$			
Treatment	Diet	7.54	0.229	7.09	7.99
	Tablet	8.98	0.141	8.70	9.26
	Insulin	8.79	0.133	8.53	9.05
		$p < 0.001$			
Social class*	1, 2	8.26	0.151	7.96	8.56
	3, 4, 5	8.67	0.170	8.34	9.00
	9	8.51	0.159	8.20	8.82
		$p = 0.025$			
Years diagnosed	< 5	8.76	0.168	8.43	9.09
	5–10	8.43	0.154	8.13	8.73
	11–20	8.38	0.182	8.02	8.74
	21–29	8.37	0.236	7.91	8.83
	> 30	8.24	0.153	7.94	8.54
		$p < 0.001$			
BMI	< 20	8.78	0.322	8.15	9.41
	20–25	8.15	0.148	7.86	8.44
	25–30	8.29	0.136	8.02	8.56
	> 30	8.53	0.143	8.25	8.81
	df = 3	$p = 0.01$			

* *For a subsample of patients, social class was not classifiable from the information given, e.g. patients who had retired but did not give a previous occupation. Rather than excluding them from the analysis, such patients were allocated a separate social class (9)*

df = degrees of freedom

for a population of patients. While a change of 0.35% may not be regarded as a significant change for an individual patient, for a population such a change may be sufficient to be regarded as clinically significant.

Is this improvement in control caused by bias in the selection of subjects?

Selection bias in a cohort study has been defined as being:

> "...where the choice of exposed and non-exposed individuals is related to their development of the outcome of interest." [28]

In this study selection bias would therefore exist if the choice of patients at Guy's and St Thomas's Hospitals differed according to the level of glycaemic control. The first inclusion criteria was for patients selected to have attended the diabetes clinic between October 1995 and March 1996. This sampling technique was

chosen because, at Guy's Hospital, patient records were only accessible for these patients. The inclusion criteria was applied to patients at both hospitals to minimise the possibility of selection bias between them. The application of the same inclusion criteria to patients from both hospitals would seem to minimise the possibility of selection bias affecting the internal validity of the results.

Secondly, the principle analysis was conducted on those patients with complete clinical records for the parameters required to assess case-mix and intermediate outcome. The exclusion of patients for whom these data were not available would seem to have led to selection bias. The mean difference in HbA_{1C} levels between the hospitals for the initial sample of patients was 0.87. For patients who met the inclusion criteria, the uncontrolled difference was only 0.43. This was because the patients excluded at St Thomas's Hospital had a mean HbA_{1C} level which was higher than those who were included. The implication of this finding is that selection bias is likely to have caused an underestimation of the difference in the mean HbA_{1C} result between the two locations.

Can the difference be attributed to the presence of confounding factors?

The study design chosen controlled for differences in case-mix between the two sites. However, there may be uncontrolled confounding factors which could account for some or all of the differences observed. Such possible differences between the two hospitals include the availability of other technologies, the difference in clinical protocols and the experience of the physicians concerned. The possible effectiveness of NPT compared with conventional testing can only be accurately measured using a prospective study design.

When the study design for this project was chosen, the choice of using a prospective study design was considered. The reasons why such a design was not adopted at that stage are outlined in chapter 1. The observed difference in intermediate clinical outcome may mean that it is now considered desirable to quantify any change in glycaemic control associated with the introduction of NPT using a prospective RCT.

Conclusion

The retrospective cohort study showed that after controlling for certain confounding factors, the mean HbA_{1C} level was lower in the clinic where test results were provided immediately. Whether this observed difference in clinical outcome can be directly attributed to NPT is less certain. In order to precisely quantify the effect of the testing system on HbA_{1C} level, a prospective RCT is required.

The purpose of the retrospective study was to generate evidence to decide whether or not such a trial should take place. Its results need to be set alongside those presented in chapters 2–4, which indicate that NPT provides timely information for supporting patient management and leads to more management changes in patients with poor control. None of these strands of evidence provide 'proof' that NPT leads to improved clinical outcome in patients with diabetes but they do indicate that a prospective RCT of the impact of NPT on HbA_{1C} levels in patients with diabetes may now be justified. However, a recommendation to devote resources to research in this area cannot be taken without first considering the results relating to the costs of NPT.

Summary

- A retrospective cohort study compared mean HbA_{1C} levels between NPT and conventional testing groups.
- The mean HbA_{1C} level was lower for a cohort of patients who attended an NPT clinic compared with a cohort of those who had been conventionally tested.
- The differences in HbA_{1C} results remained after controlling for case-mix.
- A retrospective cohort study design is unable to completely control for confounding factors.
- To measure the efficacy of the intervention requires a prospective RCT.

Chapter 6

Health service costs

Introduction

Health service costs were calculated for both conventional testing and nurse NPT at Guy's Hospital and laboratory NPT at St Thomas's Hospital. The scope of the costs was limited to those costs which were likely to be directly affected by the choice of testing system. This reflected the study's objective which was to measure the relative costs of each of the approaches rather than the absolute cost of providing a testing service for patients with diabetes. This meant that all direct clinic costs were measured for each of the three approaches. Overheads and capital charges were excluded from the analysis.

The resource use of each procedure was measured and reported separately from the costs as guidelines suggest.[29] Using this methodology facilitates the local interpretation of results. Charges were not used as a proxy for cost since they are unlikely to represent the opportunity cost.[30]

Method

Resource use measurement

Resource use data were collected prospectively for all three methods. For laboratory NPT, data were collected on 404 consecutive patients who attended the clinic between January and March 1996. Data were collected during the trial (see chapter 2) on 302 patients who had nurse NPT (Group A) and 297 patients who were conventionally tested (Group B).

Resource use was measured using either a 'bottom up' or 'top down' approach.[31] A bottom up approach was taken if an item of resource use could be accurately measured for an individual patient. The laboratory tests for each patient were recorded from laboratory records and the corresponding time spent by the research nurse, phlebotomist and laboratory technicians was then calculated for each patient visit. Doctor's time and the number of visits each year were derived from patient questionnaires handed out at the clinic (see chapter 7).

For certain items of resource use it may be inaccurate to measure resource use on an individual basis[32] and it may be better to take a top down approach. General nursing time and the use of capital equipment were measured in this way. Average nursing time was calculated by dividing the total nursing time at the clinics by the total number of patients who attended.

The use of each item of capital equipment was attributed to a patient visit on the basis of the number of tests processed for the patient on each item of equipment.

For the nurse NPT system, the nurses had training sessions with the equipment manufacturers before the system was introduced. The cost of this training was excluded from the analysis to ensure a consistent comparison was made with the two existing systems for which the cost analysis did not include these costs. The cost of quality control, a recurring cost for any of the testing methods, was included in the analysis.

Average clinic costs

The relevant cost was assigned to each item of resource use. For reagents and equipment, 1996–97 prices were taken from manufacturers' price lists, including VAT. The annual cost of equipment was estimated using a 7-year lifespan and a discount rate of 6%. Staff salaries were taken from finance office records and included on-costs of 18% but excluded London weighting. The variable and fixed costs were summed to give an average cost per patient visit.

Average annual costs

The average visit cost was multiplied by the number of visits per year to give an average annual cost.

Incremental costs

A comparison of the average costs of the three strategies is of limited value to the provider of health care who has to decide whether to adopt either of the NPT strategies to replace a conventional testing system. Simply comparing average costs ignores the effects of volume on cost. To take account of this problem, the marginal cost of different interventions can be compared.[29]

In this analysis the relevant unit of production is the testing service *per se*, so the notion of differential cost rather than marginal cost is incorporated into the analysis. Differential cost is the incremental cost for a given volume.

The baseline differential cost analysis (scenario A) measured the annual incremental costs of providing a testing service for 1500 patients – the approximate number who attended the routine diabetes clinics at each of the two hospitals investigated.

Sensitivity analysis

Sensitivity analysis is a technique which has been recommended for extending the generalisability of the results of a study.[33]

In this study, sensitivity analysis was conducted by varying the following key variables:

- frequency of test requests for nurse NPT (scenario B)
- length of follow-up (scenario C)
- presence of a parent laboratory (scenario D)
- range of test results (scenario E)
- volume of patients tested (scenario F).

The results for each scenario are presented individually and in a summary table.

Results

Resource use per visit

Compared with conventional testing, both NPT approaches were associated with more tests, more qualified laboratory technician time and more research nurse time (*Table 19*).

Average cost per visit

The mean costs per clinic are presented in *Table 20*. The average cost for both NPT approaches was higher than for conventional testing.

The mean differences between the systems are presented in *Table 21*. The average clinic costs were significantly higher for both NPT approaches. The higher costs of NPT approaches were partly due to the higher number of tests processed but also to the higher unit costs for capital equipment for NPT.

Of the two NPT methods, nurse NPT was significantly more expensive. The principal reason for this was that the price of reagents was much higher; for example, for HbA_{1C} the price is £3.46 compared with £2.38 for either of the laboratory testing methods (see appendix 3 for a complete breakdown of resource use and cost).

TABLE 19 *Resource use for each testing system per clinic visit*

	Conventional (*n* = 297)		Laboratory NPT (*n* = 404)		Nurse NPT (*n* = 302)	
	Mean	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**
Number of tests						
Glucose	1	(0.06)	1	(0.06)	1	(0.08)
HbA_{1C}	0.31	(0.46)	1	(0.06)	1	(0.06)
Cholesterol	0.21	(0.41)	0.76	(0.43)	1	(0.06)
Triglyceride	0.20	(0.40)	0.75	(0.43)	1	(0.08)
Creatinine	0.30	(0.46)	0.75	(0.43)	0.68	(0.47)
Testing staff time (hours)						
Research nurse	0	(0)	0	(0)	0.17	(0.01)
Qualified laboratory technician	0.03	(0.04)	0.18	(0.06)	0	(0.01)
Unqualified laboratory technician	0.14	(0.08)	0	(0)	0.17	(0.01)
Phlebotomist	0.14	(0.08)	0	(0)	0.17	(0.01)
Unqualified nurse	0	(0)	0	(0)	0.34	(0.02)
Other staff time (hours)						
Qualified nurse*	0.16	(0)	0.23	(0)	0.16	(0)
Unqualified nurse	0.54	(0)	0.23	(0)	0.40	(0)
Doctor†	0.26	(0.14)	0.31	(0.11)	0.24	(0.12)

* *For the general nursing staff, the time spent with the patient was assumed to be constant*

† *Doctor's time is based on the responses to the patient questionnaire; the response rate was 70% for laboratory NPT and 69% for both other approaches*

TABLE 20 *Average cost per visit of providing each testing service*

	Conventional (£)	Laboratory NPT (£)	Nurse NPT (£)
	Mean (SD)	**Mean (SD)**	**Mean (SD)**
Reagents	1.51 (1.21)	2.57 (0.22)	8.82 (1.34)
Staff	12.24 (4.52)	12.15 (3.13)	14.54 (3.26)
Fixed	0.26 (0.31)	3.08 (0.94)	3.24 (2.06)
Cost per visit	**14.0 (6.05)**	**17.80 (4.28)**	**26.60 (6.65)**

TABLE 21 *Differences between mean costs per visit for the three strategies*

Difference between:	Mean (£)	95% CI
Laboratory NPT and conventional	3.80	2.99–4.60
Nurse NPT and conventional	12.60	11.79–13.40
Nurse NPT and laboratory NPT	8.80	7.94–9.66

TABLE 22 *Annual incremental cost for scenario A: the baseline case*

Testing system	Cost per visit (£)	Visits per year	Mean total cost (n = 1500) (£)	Incremental cost (£) (95% CI)
Conventional (GH)	14.0	2.28	47,885	47,885 (46,839, 48,931)
Laboratory NPT (TH)	17.8	1.81	48,315	434 (–801, 1668)*
Nurse NPT (GH)	26.6	1.81	72,211	24,326 (23,509, 25,143)

* *The incremental costs of both NPT strategies are always measured relative to the conventional testing system*

Average cost per year

The mean number of visits per year (SD) was 2.28 (1.01) for conventional testing and 1.81 (1.20) for laboratory NPT (see chapter 7 for details of how these figures were derived). The corresponding annual costs per patient were therefore £31.92 for conventional testing and £32.22 for laboratory NPT. This meant that the mean difference in annual costs between these two approaches was not significant (mean = £0.31: 95% CI, –£0.51, £1.13).

Incremental cost analysis

For the incremental cost analysis the objective was to measure the likely difference in total cost per year for each of the three strategies. For the base case this meant two assumptions were made:

(i) 1500 patients per year attended each of the clinics
(ii) frequency of clinic visits for nurse NPT was assumed to be the same as for laboratory NPT.

The total cost of conventional testing was then calculated as follows:

$$\text{total cost} = (\text{average visit cost}) \times (\text{visits per year}) \times 1500$$

The incremental cost of conventional testing was then calculated relative to a 'do nothing' approach. The incremental cost of both NPT approaches was then calculated taking conventional testing as the baseline.

Mean incremental costs of conventional testing:
£47,885 – 0 = £47,885

Incremental cost for laboratory NPT:
£48,315 – £47,885 = £434

Incremental cost for nurse NPT:
£72,211 – £47,885 = £24,326

From *Table 22* it can be seen that the incremental cost of laboratory NPT compared with conventional testing was non-significant, whereas nurse NPT cost on average £24,326 more than conventional testing.

Sensitivity analysis

The sensitivity analysis examines the extent to which the conclusions drawn are sensitive to the assumptions made. Conventional testing is always used as the baseline for the incremental costs of the two NPT approaches.

Scenario B: frequency of test requests

In scenario A, the costs of conventional testing and nurse NPT were taken from the trial at Guy's Hospital. This may have led to a 'trial effect' as resource consumption under normal conditions may be different. In particular, the number of tests requested under the nurse NPT system may have been higher in the trial than would be the case if the system was introduced into routine practice. To counter this, the number of tests requested in scenario B for nurse NPT is assumed to be the same as for laboratory NPT. This mainly has the effect of reducing the reagent costs and fixed

TABLE 23 *Scenario B: eliminating the 'trial effects'*

Testing system	Cost per visit (£)	Visits per year	Mean total cost (*n* = 1500) (£)	Incremental cost (£) (95% CI)
Conventional (GH)	14.0	2.28	47,885	47,885 (46,839, 48,931)
Laboratory NPT (TH)	17.8	1.81	48,315	434 (–801, 1668)
Nurse NPT (GH)	22.7	1.81	61,500	13,615 (12,057, 15,173)

TABLE 24 *Scenario C: visit frequency is constant*

Testing system	Cost per visit (£)	Visits per year	Mean total cost (*n* = 1500) (£)	Incremental cost (£) (95% CI)
Conventional (GH)	14.0	2.28	47,885	47,885 (46,839–48,931)
Laboratory NPT (TH)	17.8	2.28	60,865	12,980 (11,746–14,215)
Nurse NPT (GH)	22.7	2.28	77,470	29,585 (28,600–30,569)

costs associated with this approach. The mean cost per visit (SD) for nurse NPT therefore falls from £26.6 (6.65) per visit to £22.7 (5.89). The effect on the incremental cost is shown in *Table 23*: nurse NPT still has a large positive incremental cost.

Scenario C: varying the visit frequency

The analysis up to this point assumes that both NPT approaches lead to a fall in the number of visits from 2.28 to 1.81 per annum. In scenario C, it is assumed that the number of visits are constant across all three approaches (*Table 24*).

Relaxing the assumption that NPT reduces the number of clinic visits means that the incremental cost for both NPT methods is significantly positive; the mean incremental cost is now £12,980 for laboratory NPT and £29,585 for nurse NPT.

Scenario D: no parent laboratory

In the baseline analysis, the close proximity of a central laboratory to the diabetes clinic means economies of scope exist for both NPT strategies. The central laboratory provided staff for the laboratory NPT system while the clinic was in progress and assisted with quality control in nurse NPT. If there is not a central laboratory nearby, then these economies of scope may be lost. Scenario C considers two important additional costs which would be present for a 'satellite' NPT system.

1. ***The cost of employing a full-time technician for laboratory NPT*** In the baseline case, a qualified laboratory technician was available to work part of the time in the diabetes clinic and the remainder of the time in the centralised laboratory. In scenario C, laboratory NPT is assumed to require a full-time laboratory technician.
2. ***An external quality control contract for nurse NPT*** In Scenario A, the proximity of a central laboratory enabled a qualified laboratory technician to monitor quality control without imposing any significant additional costs on the system. A satellite laboratory which required an external quality control contract would incur an additional cost of about £2000 per annum.

The incremental costs are higher for both NPT approaches when there is no centralised laboratory nearby (*Table 25*). For the laboratory NPT approach the requirement to employ a full-time qualified technician caused staff costs to rise considerably. This meant that under this scenario, even if the frequency of visits was reduced, the incremental costs of laboratory NPT are likely to be positive.

For the nurse NPT approach, the fixed costs rose as the outside quality control contract would prove to be much more expensive than supervision from an adjacent laboratory. This is reflected in the high incremental costs irrespective of visit frequency.

Scenario E: NPT for HbA_{1C}, conventional testing for other tests

The findings of this study (see chapter 2) suggest that there is no significant improvement in the clinical process from having immediate results available for lipids and creatinine. In scenario D, the costs of providing HbA_{1C} by NPT and all other results by conventional testing were compared to supplying all results by conventional testing. The volume of lipid and creatinine tests requested are assumed to fall to the levels of the baseline conventional testing approach. This reduction in the overall volume of tests has certain implications for the resources required for this approach compared with the baseline case.

TABLE 25 *Scenario D: no parent laboratory*

Testing system	Cost per visit (£)	Visits per year	Mean total cost (*n* = 1500) (£)	Incremental cost (£) (95% CI)
Conventional (GH)	14.0	2.28	47,885	47,885 (46,839–48,931)
Laboratory NPT (TH)	23.65	2.28	80,872	32,987, (31,753–34,222)
Nurse NPT (GH)	23.90	2.28	81,745	33,860 (32,875–34,844)
Laboratory NPT (TH)	23.65	1.81	64,201	16,316 (15,081–17,551)
Nurse NPT (GH)	23.90	1.81	64,894	17,009 (16,024–17,993)

TABLE 26 *Scenario E: NPT for HbA_{1C}, conventional testing for the other tests*

Testing system	Cost per visit (£)	Visits per year	Mean total cost (*n* = 1500) (£)	Incremental cost (£) (95% CI)
High frequency of visits				
Conventional (GH)	14.0	2.28	47,885	47,885 (46,839–48,931)
Laboratory NPT (TH)	15.62	2.28	53,410	5525 (4290–6760)
Nurse NPT (GH)	17.91	2.28	61,252	13,367 (12,475–14,259)
Low frequency of visits (NPT)				
Conventional (GH)	14.0	2.28	47,885	47,885 (46,839–48,931)
Laboratory NPT (TH)	15.62	1.81	42,400	–5485 (–6720, –4250)
Nurse NPT (GH)	17.91	1.81	48,625	740 (–164, 1644)

- This reduction in the volume of tests reduces the quantity of reagents required for both NPT strategies.
- For laboratory NPT, there is a reduction in technician's time and for nurse NPT, a research nurse is no longer required.
- For both NPT sites there is a switch in the capital equipment required from 'on site' equipment (high unit costs) to centralised laboratory equipment (low unit costs).

The effect of these changes is quantified in *Table 26* which shows that for laboratory NPT the unit cost per visit is £2.18 lower than for the baseline case, whereas for nurse NPT the corresponding fall is £4.79. A precise breakdown of the costs incurred in this scenario are shown in appendix 3. For both NPT strategies there is an important reduction in fixed costs and for nurse NPT there is a significant fall in the reagent costs associated with this approach. Staff costs fall under scenario E, although this is not the dominant effect.

The least costly option for this strategy is still conventional testing unless the number of visits falls. If this is the case then laboratory NPT is the cheapest strategy.

Scenario F: low volume of patients

In the previous analysis, the incremental costs of providing each testing service were considered for 1500 patients. However, incremental cost is likely to vary with volume.[34] In scenario E, the effect of a reduced volume on incremental cost is considered. Since, in the baseline case, a very high volume of patients was considered, in this scenario the impact of a low volume of patients on the relative costs of the main approaches is considered. This analysis assumed that certain important determinants of cost, such as the length of follow-up and the mean number of tests requested, were not necessarily dependant on volume. The most important capacity constraint was considered to be the staffing levels at a clinic and the equipment available for providing an NPT service. Rather than considering a completely hypothetical situation, the staffing levels of a district general hospital were used to model the costs of each of the three systems. Since such a hospital is unlikely to run a full NPT service for patients with diabetes, the relative costs of providing an HbA_{1C} only NPT service were modelled. Scenario D is the relevant comparator to consider the effect of volume on relative costs.

The Kent and Sussex Hospital was used to model this scenario; on average, 17.5 patients per week attended the diabetes clinic. The staffing complement at this clinic consisted of three doctors, a phlebotomist, and three nurses (two qualified and one unqualified). From the earlier evidence (see chapter 2), these staff were considered sufficient to run either form of NPT system.

TABLE 27 *Scenario F: low volume of patients*[*]

Testing system	Cost per visit (£)	Visits per year	Mean total cost (n = 1500) (£)	Incremental cost (£) (95% CI)
High frequency of visits				
Conventional[*]	14.73	2.28	50,377	50,377 (49,777–50,976)
Laboratory NPT	24.11	2.28	82,440	32,063 (31,418–32,708)
Nurse NPT	17.76	2.28	60,750	10,373 (9754–10,992)
Low frequency of visits				
Laboratory NPT	24.11	1.81	65,446	15,069 (14,424–15,714)
Nurse NPT	17.76	1.81	48,227	–2150 (–2769–1531)

[*] *Staff from the Kent and Sussex Hospital were used to model the costs for this approach*

TABLE 28 *Summary of the results from the sensitivity analysis*

Scenario	NPT visit frequency	Dominant cost strategy
Baseline (A)	Low	Conventional/laboratory NPT
No trial effect for nurse NPT (B)	Low	Conventional/laboratory NPT
Constant visit frequency (C)	High	Conventional
No parent laboratory (D)	Low High	Conventional Conventional
HbA_{1C} only for NPT (E)	Low High	Laboratory NPT Conventional
Low patient volume (F)	Low High	Nurse NPT Conventional

The results shown in *Table 27* suggest that for a low volume of patients, nurse NPT has a cost per visit of £17.76 compared with £24.11 for laboratory NPT (see appendix 3 for the breakdown of the results). Thus, the laboratory NPT strategy becomes relatively more expensive in the low volume scenario, due to the loss of economies of scale. This means that compared with scenario D the fixed costs per unit of this approach are much higher. For nurse NPT, the low volume clinic would be able to use one DCA analyser rather than two, so the fixed costs per unit are similar to those of scenario D.

The incremental cost analysis shows that if NPT can be assumed to reduce visit frequency, then the introduction of nurse NPT instead of conventional testing may lead to lower costs. However, the analysis suggests that for laboratory NPT the incremental costs will still be positive.

Discussion

The perspective taken in this costing exercise was of the healthcare decision maker who has to decide which testing service to provide for patients with diabetes. In the baseline analysis, which measures the health service costs of the scenario directly observed in the study, the incremental costs were positive for both NPT strategies. The incremental cost was highest for nurse NPT, primarily because this approach was characterised by high reagent costs and also by patients visiting the clinic as often as for conventional testing.

The sensitivity analysis (for which the results are summarised in *Table 28*) was intended to provide broad estimates as to how the relative costs of each strategy may vary according to the assumptions made. The analysis suggests that the strategy which is dominant in cost varies according to the particular scenario considered. Three important determinants of the relative cost of the various testing approaches are:

- the frequency of patient visits
- the range of tests provided by NPT
- the setting within which NPT is introduced.

Frequency of patient visits

Patients visited the diabetes clinic less frequently at St Thomas's Hospital where there was a NPT service than at Guy's Hospital where there was a conventional testing system. The extent to which the reduced visit frequency at St Thomas's Hospital may have been attributable to the testing system cannot be precisely stated. However, this result does appear to substantiate the evidence from the providers' interviews which suggested that providing immediate test results may reduce the frequency with which patients are required to visit the diabetes clinic. The impact the reduction in visit frequency would have on costs is shown in scenario B. Moving from a situation in which the testing facility has no impact on visit frequency to a situation in which all the observed difference in visit frequency is attributable to the testing system, reduces the incremental costs of NPT by about 75%.

The extent to which the introduction of an NPT system may reduce the frequency of follow-up is likely to depend on how sensitive staffing levels are to changes in demand. At Guy's Hospital, following the introduction of nurse NPT, the frequency of visits in the ensuing 3 months remained unchanged. This may have been because, in the short term, the staffing levels at the clinic are fixed. If there are still the same number of doctors working at a clinic, they may not change the appointment frequency. This decision may reflect the resources available rather than the most appropriate referral rate for the patient.

Range of tests provided by NPT

Providing an NPT system for just HbA_{1C} results in lower costs than introducing NPT for a battery of tests. If the introduction of an NPT system can be used to reduce the frequency of visits to the level hypothesised, then the introduction of this particular system may not increase costs. The additional costs of providing lipids and cholesterol testing using NPT appears less likely to be justified by improvements in the process of care (chapter 2).

The setting in which NPT is introduced

The cost of introducing either NPT approach rises considerably if the necessary staff cannot be employed from the central laboratory just for the diabetes clinic. This is an important consideration for a decision maker looking to decide if it is cost-effective to introduce NPT.

The number of patients with diabetes who attend the clinic is also an important determinant of the relative incremental cost of each strategy. For a low volume of patients, nurse NPT was the least costly NPT strategy. Further work in this area would be useful to derive the marginal cost curve for each strategy.

Conclusion

While the sensitivity analysis does not attempt to provide an incremental cost analysis for every potential decision maker, it does provide a framework from which the relevant costs can be derived for the particular local setting concerned. The direct result of this study was that if HbA_{1C}, lipids and creatinine were provided by NPT then visit costs were higher. Compared with conventional testing, the mean visit costs were £3.80 higher under laboratory NPT and £12.60 higher under nurse NPT, reflecting the greater number of tests conducted at NPT visits. This finding is in line with a previous study[1] which suggests that, in general, NPT increases costs. When the NPT service was provided just for HbA_{1C} results, the additional mean visit costs of NPT are lower; laboratory NPT costs an extra £1.62 and nurse NPT an additional £3.91. The introduction of an NPT by a provider without direct access to a central laboratory meant that the additional cost of the system rose to £9.65 for laboratory NPT and £9.90 for nurse NPT. The only costing scenario under which NPT led to lower short-term costs involved reducing the frequency of patient visits and only testing for HbA_{1C}. Although the introduction of NPT may reduce visit frequency, any corresponding effects on the overall quality of care provided must be carefully evaluated.

Summary

- The mean cost of the three approaches was compared.
- The cost per visit was lowest for conventional testing followed by laboratory NPT then nurse NPT.
- The sensitivity analysis showed that the strategy which was dominant in cost varied according to:
  - visit frequency
  - the range of tests offered under NPT
  - the setting concerned.

Chapter 7

The impact of NPT on patient costs

Introduction

If the perspective of the healthcare system is adopted for the evaluation of a given technology, then the scope of costs included is often restricted to those borne directly by the health sector. However, it is usually preferable to adopt a societal viewpoint, particularly where there are likely to be significant patient costs associated with a particular condition or service change.[31] Hence, a study of the role of NPT in diabetes care should include an assessment of its impact on patient costs.

The literature reviewed in chapter 1 of this report indicated that NPT may affect the number of visits that patients make to healthcare settings which, in turn, may affect the overall amount of time and resources that they must devote to attending clinics. When assessing such patient costs, the most meaningful unit of patient inputs is time. This makes it easier to generalise the findings of a study. It avoids the problem of study findings being affected by, for example, the socio-economic characteristics of the local population of the study setting, which would occur if patient inputs were measured solely in terms of financial expenditure.

Methods

A self-completed patient questionnaire was developed to collect data related to patient costs (see appendix 2). The questionnaire was given to all patients attending both conventional and laboratory NPT clinics over the period January–March 1996 and to all those attending the nurse NPT clinic over the period July–September 1996. The questionnaire was given to patients by a member of the research team when they arrived at the hospital clinic and they were asked to return the completed questionnaire when they left the clinic.

For each of the three testing strategies the patient questionnaire collected details of the duration of the current hospital clinic visit, in terms of waiting time, time having tests taken and time spent with healthcare professionals. For the laboratory NPT and the conventional service, the patient travel time associated with the visit was also recorded.

Patients attending the laboratory NPT service at St Thomas's Hospital and the conventional service at Guy's Hospital were asked how many routine visits to diabetes clinics they usually made per year. In addition, using HbA_{1C} as a marker test, patients attending the Guy's Hospital conventional service were asked when and how they usually received their test result. HbA_{1C} was chosen as the marker test because of its important role in the measurement of diabetes control and because it complemented the research relating to the impact of NPT on clinical outcome.

The patient questionnaire was piloted before its formal use in the research study. In the initial questionnaire, patients were asked about the time and resources they incurred from making subsequent visits to other healthcare settings, such as general practice clinics, to obtain test results. Since the patients' use of these other services were not found to be dependant upon the method of testing, these items were omitted from the final study instrument.

Results

The patient questionnaire was given to 428 users of the conventional testing service, 403 users of the laboratory NPT service and 404 users of the nurse NPT service. Aspects of the questionnaire were completed by 288 individuals for the conventional strategy (response rate 67%), 307 users of the laboratory NPT service (response rate 76%), and 280 users of the nurse NPT service (response rate 69%). There was no significant difference between responders and non-responders in terms of the level of HbA_{1C}.

In *Table 29*, conventional and laboratory NPT clinic times per diabetes appointment are compared in terms of waiting time, time taking tests and time with healthcare professionals. The mean for each parameter is derived from the number who responded to the relevant question. The number who responded to all of the relevant questions is shown in the table. The total time for each strategy is calculated from those patients who responded to all the relevant questions.

TABLE 29 *Resources used by patients in attending conventional and laboratory NPT clinics (values are shown as mean time in minutes (SD))*

Item of resource use	Conventional testing (GH) $n \geq 216$	Laboratory NPT (TH) $n \geq 232$
Waiting time	44.1 (29.6)	49.9 (30.3)
Time with doctor	15.4 (8.5)	18.3 (10.6)
Time taking tests	13.8 (14.3)	10.1 (11.6)
Total visit time per clinic	72.3 (33.6)	77.4 (33.3)

TABLE 30 *Resources used by patients in attending conventional and nurse near patient diabetes clinics (values are shown as mean time in minutes (SD))*

Item of resource use	Conventional testing (GH) $n \geq 216$	Nurse NPT (GH) $n \geq 216$
Waiting time	44.1 (29.6)	41.0 (24.8)
Time with doctor	15.4 (8.5)	14.4 (7.4)
Time taking tests	13.8 (14.3)	21.2 (14.2)
Total visit time per clinic	72.3 (33.6)	75.6 (33.4)

The mean total visit time was similar for both strategies. The laboratory NPT strategy had a slightly longer duration than the conventional strategy because patients indicated that they had an increased waiting time and spent longer with the doctor, although the time taking tests was shorter.

Rather than being due to NPT *per se*, these results relating to clinic duration may reflect more general differences in the way services are delivered at the two hospitals. To help avoid this potential problem, the results in *Table 30* compare clinic duration per patient for the Guy's Hospital conventional and nurse NPT services.

Again, the results in relation to clinic duration are similar for the two strategies. Patients receiving the nurse NPT service indicated that they now spent less time waiting but more time having tests taken.

When asked how many times per year they attended hospital diabetes clinics, patients attending the laboratory NPT service indicated that they made fewer visits than those attending the conventional service. The mean numbers of visits per patient per year were 1.81 (SD 1.20) at St Thomas's Hospital compared with 2.28 visits (SD 1.01) at Guy's Hospital. Although the data were not normally distributed, the relatively large sample size meant a normal approximation could be used when testing for statistical significance. The difference in the mean number of hospital clinic visits per patient per year was statistically significant (95% CI of difference in the means, 0.234–0.606).

A total of 118 patients (55%) at Guy's Hospital said they had been tested for HbA_{1C} at their previous clinic visit. They were asked how they had been given their test result. Of the 118 patients, 46% (54) indicated that they had received their result at the same clinic, reflecting the prior existence of a limited NPT service, 14% were informed of their result at their next hospital clinic, 2% at an extra clinic appointment, 2% received their result by post, 8% by some 'other' means, 17% did not receive their result, and 11% did not respond.

Conventional testing, as practised in this hospital, did not therefore seem to result in patients making additional visits to non-hospital settings in order to receive their test results. The finding is further confirmed by the results presented in chapter 2. These indicated that letters sent by hospital clinicians to GPs only included test results that were available at the time of the clinic and, hence, results that could have been transmitted directly to the patient. Thus, patients would not gain extra test information from their clinic consultation by visiting their GP.

The observed difference between the conventional and laboratory NPT strategies in the annual number of hospital clinic visits per patient has important implications. In terms of patient costs, the mean annual clinic time per patient (clinic duration × visits per annum) is 142 minutes for the nurse NPT strategy and 167 minutes for the conventional strategy. The difference is greater when patient travel time per clinic appointment are included. Mean travel time per appointment for both hospitals is 87.2 minutes. When travel time and clinic times are combined, the mean annual time associated with clinic visits per patient is 300 minutes for the NPT strategy and 366 minutes for the conventional strategy. However, this difference was not found to be statistically significant ($p = 0.1539$).

Discussion

Patient costs represent a key input that an individual must contribute to their care. For a chronic condition, such as diabetes, the

scale and importance of these costs is likely to be greater.

All three strategies had broadly similar clinic times per patient visit. However, patients using a conventional testing service made significantly more clinic visits per annum than those using an established NPT service. The mean annual visit time per patient was also 22% greater under conventional testing, although the spread of the results meant that this difference was not statistically significant. From an individual patient perspective, however, more clinic visits imply more time consumed by diabetes care.

Patient cost results were presented in units of time to increase their generalisability to other settings. However, in addition to time, these extra visits are likely to have had potential financial implications for patients in terms of, for example, travel costs and loss of earnings. Although not presented in this report, from an individual patient perspective such financial costs are important and further increase the potential benefits of NPT.

The key issue is whether or not the observed differences in patient costs are a consequence of the NPT strategy. The results presented here do suggest that there may be a link between NPT and a reduced number of visits per year. Although 19% of patients in the conventional testing strategy did receive test results at the same clinic, this reflected the introduction of an NPT system for a minority of patients. For the rest of the patients they either did not have a test done, or they had to wait until their next clinic for the result. From the point of view of patient costs, the conventional testing approach may have increased costs because patients were having to make more frequent visits to the clinic in order to discuss results. The conventional testing approach did not seem to lead to more visits by the patients to their GPs to collect results.

Conclusion

The results presented here indicate that patient costs per clinic visit are similar for NPT and conventional testing strategies. If it is accepted that NPT leads to a lower frequency of patient visits to clinics, then NPT can bring about a substantial reduction in the annual patient costs of diabetes care. However, it is important that the overall quality of the service is carefully monitored.

In the conclusion of chapter 5, it was argued that a prospective RCT may now be needed to firmly establish whether or not NPT leads to improved clinical outcomes in patients with diabetes. Such a trial should also compare the costs of different testing strategies. The results presented in chapters 6 and 7 have demonstrated that the frequency of patient visits to clinic has a key impact on both health service and patient costs. Hence, any future trial should seek to establish the link between NPT and the annual number of visits that patients make to diabetes clinics.

Summary

- Patient questionnaires were used to measure the patient costs associated with each strategy.
- Patient time per clinic visit did not differ significantly between the different approaches.
- Patients visited the laboratory NPT clinic less often than the conventional testing clinic.
- The increased number of visits under conventional testing may have been because of the need to visit the clinic more often to collect results.
- The difference could also be caused by differences in clinical protocols between the two hospitals.
- A prospective RCT is needed to firmly establish the link between NPT and the frequency with which patients need to attend diabetes clinics.

Chapter 8

Costs and consequences of NPT in diabetes clinics: a review of the evidence

Introduction

In this study, the costs and consequences of three strategies for providing test information for the care of individuals with diabetes have been compared – conventional testing as practised at Guy's Hospital, laboratory NPT as practised at St Thomas's Hospital, and nurse NPT as piloted at Guy's Hospital.

The study employed a range of methods in order to provide information on the following issues:

(i) the impact of NPT on the process of care and the accuracy of testing
(ii) the impact of NPT on patient satisfaction
(iii) the views of health service professionals on the different approaches to testing
(iv) the impact of NPT on clinical outcome measured by the mean difference in HbA_{1C} levels between patients using conventional and NPT strategies
(v) health service costs of providing each testing service
(vi) patient costs associated with each approach.

The main conclusions of the study in relation to each of these issues are briefly reiterated here, together with the key issues that are still to be resolved.

Findings

The impact of NPT on the process of care

Patients with poor diabetes control were significantly more likely to have a change made to their management if they had access to NPT rather than conventional testing. This suggests that clinicians may not receive test information at an optimal time for decision making under conventional testing. The impact of these changes in management on the overall costs and clinical outcomes of care is currently uncertain.

The impact of NPT on the accuracy of testing

In general, the use of NPT did not affect the accuracy of the information provided for patient care.

The impact of NPT on patient satisfaction

Users of both NPT services were significantly more satisfied with the information given to them by health service staff at clinics. Patients were more likely to be given the result of an HbA_{1C} measurement if they had access to NPT and they regarded this information as important.

Clinical attitudes towards the introduction of NPT for the care of patients with diabetes

Clinicians had positive attitudes towards the introduction of NPT for the measurement of HbA_{1C}. The potential advantages of NPT that they saw included more informed decision making in relation to patient care and reduced patient visits to clinics. Clinicians considered that conventional testing was adequate for lipids, creatinine, triglycerides and cholesterol. Clinicians were also concerned that NPT could lead to organisational delays within clinics (although this concern was not borne out by other aspects of the study).

The impact of NPT on clinical outcomes in terms of HbA_{1C} levels

This issue is still to be resolved, although a number of the findings of this study support a hypothesis that NPT might lead to improved clinical outcomes. These findings were as follows.

- For patients who had 'poor' diabetes control, that is, those in whom a change in patient management might be indicated, significantly more changes were implemented when requests were analysed using NPT (see chapter 2).
- Under NPT, any required changes in patient management appeared to be implemented during the patient's hospital appointment, that is, they were based on test results that became available during the clinic (see chapter 2).
- Compared with the conventional testing service, substantially more users of an NPT service had an awareness of information directly relevant to diabetes control. This is because more of these patients had been tested for HbA_{1C} and received the result (see chapter 3).

- A sample of doctors who were interviewed stated that immediate access to test results meant that they could make more informed decisions about what changes in management should be implemented. They also considered that without immediate access to test results, changes in patient management might be sub-optimal (see chapter 4).
- After controlling for key case-mix variables, users of an established NPT service achieved better diabetic control, in terms of levels of HbA_{1C}, than users of the conventional service (see chapter 5).

When this research project began the scientific literature did not indicate that the measurement of clinical outcome should be the central focus of the study. Thus the timescale and costs of the study were dictated by its other elements.

To explore the clinical implications of NPT, a retrospective study design was adopted (see chapter 1); it was accepted that the results of that element of the project would be to provide a clearer understanding of whether or not NPT leads to improved clinical outcomes, rather than to establish whether or not such a link exists.

The way to establish whether or not NPT leads to better diabetic control would be to conduct a prospective RCT. The results of this study suggest that such a trial may now be justified.

The impact of NPT on health service costs

NPT led to a higher utilisation of tests and to higher costs per clinic visit. However, annual costs were similar for both conventional and laboratory NPT strategies, largely because patients using the NPT service had fewer clinic visits per year. Whether or not this reduced frequency of visits is a direct consequence of NPT is unclear.

A major factor affecting the relative costs of NPT and conventional care is whether NPT is introduced for a battery of tests or just for HbA_{1C}. The results of the trial suggest that there is a negligible incremental benefit in terms of the process of care from providing test results for lipids and creatinine using NPT. Guidelines for the management of diabetes[24,25] suggest that these tests are an essential aspect of diabetes care. However, interviews with the clinicians indicates that there is little additional benefit from providing these results immediately and that conventional testing can be used to monitor these risk factors. The evidence from this trial supports the findings of an earlier study[5] that for the monitoring of most risk factors NPT is not cost-effective.

The relative costs of NPT and conventional care will also depend upon the local context. The explicit breakdown of the cost of each strategy into resource use and price provides healthcare decision makers with a clear indication of the important determinants of costs for each strategy, from which the costs that apply directly to their own setting may be deduced. In chapter 6, a sensitivity analysis was used to compare the costs of the alternative strategies after modifying the key variables surrounding the provision of services and the level of patient demand. In addition to enhancing the quality of the information provided by this report, this analysis provides a framework which others could use to assess the resource consequences of NPT in their local setting.

The impact of NPT on patient costs

Patient time per clinic visit was found to be similar for all strategies. Annual patient costs were lower for the laboratory NPT strategy because of the reduced frequency of patient visits.

The impact of NPT on the frequency of patient visits to clinics

The findings in terms of cost are heavily influenced by the impact of NPT on the frequency of patient visits to clinics. So is there is a direct link between NPT and a reduced number of visits per annum or was the observed difference simply a product of differences in clinical policies between the two hospitals?

Evidence from the various components of the study suggest that there may be a link between NPT and the frequency of patient visits.

In general, under conventional testing, results that were not available during a clinic appointment were not mailed to either the patient or their GP (see chapters 2 and 7). The users of the test information were therefore hospital doctors and the next available opportunity for the information to be used to support a management change was at the patient's next hospital appointment. This method of transmitting and using test information may mean that patients under conventional care need to be called to the clinic more frequently.

A way to resolve this issue is through a prospective RCT. The results of this study have created the rationale for such a study.

Implications of these results for other conditions

The review of the literature presented in chapter 1 led to the conclusion that more research was needed surrounding the costs and consequences of NPT. More recent publications have reinforced this finding[35,36] and also suggested that, rather than attempting to evaluate NPT *per se*, evaluations should focus on its value in specific circumstances. This view was also expressed by Hobbs in a recent editorial in the *BMJ*.[35] This report investigated the costs and consequences of NPT in routine hospital diabetes clinics, so the results are not likely to be applicable to other disease areas or settings.

Recent evaluations of NPT in other areas

A recent evaluation of the cost-effectiveness of NPT in a hospital Accident and Emergency Department suggested that although NPT did not appear to lead to improved clinical outcomes,[37] it did lead to an improvement in the care process and also had the potential to reduce costs.[38] This supports the ideas generated by this study that:

- the costs and consequences of NPT cannot be assessed in general but vary according to the disease group and test in question
- the general conclusion that NPT increases costs with no improvement in the process of care does not apply in certain settings.

In a recent review of NPT in primary care,[39] which looked at a range of different applications of NPT, it was concluded that there were few areas where evidence for the cost-effectiveness of the technology supported its introduction but that HbA_{1C} measurements in diabetes care warranted more primary research. While the results of our study are not generalisable to the primary care setting, they also suggest that HbA_{1C} for patients with diabetes requires more primary research.

Recommendations

The objective of this study was to evaluate the introduction of an NPT system for a hospital-based diabetes clinic. The report was intended to provide timely and relevant information for those considering the introduction of such systems into routine practice and to highlight those areas where further research is needed.

By demonstrating that NPT increases both the utilisation of tests and health service costs, the findings of this project have confirmed those of previous studies of NPT. The results also indicate that NPT may improve both the process of care and patient satisfaction.

In addition, the results of this research have generated important hypotheses that need to be explored in further evaluations of NPT in diabetes care. These concern the impact of NPT on clinical outcomes, measured by mean HbA_{1C}, and the frequency of patient visits to clinics. Both of these effects have potential consequences for the health service and for the patient costs of diabetes care.

Recommendations on NPT for diabetes

The results of this initial research project indicate that a prospective RCT of NPT in diabetes clinics is now needed. The aims of such a trial should be to establish:

- the impact of NPT on clinical outcomes
- the impact of NPT on the frequency with which patients visit the clinics
- the impact of any changes in the above on both the health service and patient costs of care
- the possible cost-effectiveness of providing HbA_{1C} using NPT in the primary care setting.

General recommendations

The relative cost-effectiveness of a testing method varies according to the disease group considered. The use of NPT in other disease areas should be subject to separate evaluations which are particularly likely to have a beneficial effect on the effectiveness and cost-effectiveness of patient care.

NPT for patients with diabetes was a suitable subject for evaluation because patients were required to make regular visits to health settings (with potential patient cost and satisfaction effects) and regular monitoring was thought to be beneficial for blood glucose control (with potential clinical outcome effects). Such criteria might be useful in selecting future areas for research into NPT.

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The views expressed in this paper are those of the authors, who are also responsible for any errors.

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Appendix 1

Typical letter relating to changes in diabetes management

This letter is a typical example of those sent by a hospital doctor to a patient's GP giving details of any required changes in the patient's diabetes management arising from a clinic consultation.

GUY'S HOSPITAL DIABETES UNIT

1st floor, Hunts House
St Thomas Street
LONDON SE1 9RT
Tel: 0171 955 4986

re: Hospital no: DOB: 6.03.36

Letter date: 17.06.96

Dr DAS PK
34 ROTHERHITHE NEW ROAD
BERMONDSEY
LONDON
SE16 2PS

Clinic date: 4.06.96

PROBLEM LIST

Diabetes (1992) RETINOPATHY	Other problems VIT B COMPOUND HYSTERECTOMY

This diabetic woman has gained weight and her BG control has deteriorated. Her systolic BP is also raised. I have reviewed her diet and increased her Metformin to 500 mg t.d.s. I would also be grateful if you would monitor her BP as it may need treatment. Total cholesterol is moderately raised.

SUGGESTED MEDICATION CHANGES

Drug list	**Investigations**		
METFORMIN, 500 mg t.d.s.	Blood pressure	: sitting 158/78	mmHg
		lying	mmHg
	Fundoscopy	: EYE CLINIC	
	Visual acuity	:	
	Foot at risk	: No	
	Fructosamine	:	mmol/l
	HbA_1	: 7.9	%
	Creatinine	:	µmol/l
	Cholesterol tot/hdl	: 6.9/	
	Triglycerides	:	
	Urine Alb/Cre ratio	:	

Next appointment: 6 months

Yours sincerely

PROF GC VIBERTI, MD, FRCP
PROFESSOR OF DIABETES AND METABOLIC MEDICINE

Appendix 2

Questionnaires

Patient questionnaire

This questionnaire (page 52) was given to patients at Guy's and St Thomas's Hospitals in order to compare patient satisfaction under conventional testing and laboratory NPT.

Follow-up questionnaire

This questionnaire (page 59) was given to patients at Guy's Hospital during piloting of nurse NPT.

NEAR PATIENT TESTING FOR DIABETES CARE

Patient Questionnaire

I am conducting a study on behalf of the NHS Management Executive to compare the testing facilities at Guy's & St Thomas's diabetes clinics. As part of this project, I need to measure the patient satisfaction with the existing testing facilities. I would therefore be very grateful if you would answer the following questions while you are waiting to see the doctor, and return the questionnaire to me before you leave today.

HOW TO FILL IN THE QUESTIONNAIRE

Most questions can be answered by ticking the box next to the answer that applies to you. Please tick one box only for each question, unless the question says to tick more than one.

Yes ☑

No ☐

Sometimes you are asked to circle a number.

	Not at all easy					Very easy
For example, how easy are these instructions to understand?	0	1	2	(3)	4	5

And sometimes you are asked write in an answer in your own words.

like this _____

Please fill in as much of the questionnaire as you can – if you cannot complete any parts of the questionnaire, please ask me for help.

Everything you say will be treated as strictly confidential.

A. PATIENT RESOURCE USE

I am firstly going to ask you about the time you spend visiting the doctor at the diabetes clinic for your routine review/monitoring appointment.

1. How often do you usually visit the <u>doctor at the diabetes clinic</u> for review/monitoring?

(a) Every 3 months ☐

(b) Every 6 months ☐

(c) Once a year ☐

(d) Other (please specify) _____

2. (i) Have you had to take time off work for the appointment today?

(a) Yes ☐

(b) No ☐

(ii) **If yes, how many hours?**

Time: _____ hours

(iii) **Have you lost any earnings for the time taken for this appointment?**

(a) Yes ☐

(b) No ☐

(iv) **If so, were the wages lost representative of the earnings you usually lose when taking time off work to visit the diabetes clinic?**

(a) Yes ☐

(b) No ☐

3. **Please would you estimate the time this particular appointment has involved in each of the following categories (where appropriate)**

***Please would you answer these questions after you have been in to see the doctor**

(a) **Travel time** (to the diabetes clinic) _____ mins

(b) **Waiting time** (from your appointment time until the time you see the doctor)* _____ mins

(c) **Time with doctor*** _____ mins

(d) **Time with dietician*** _____ mins

(e) **Time with eye doctor*** _____ mins

(f) **Time taking blood tests*** _____ mins

(g) **Time with nurse*** _____ mins

(h) **Other time (please specify)*** _____ mins

4. **Please would you state the travelling expenses you incurred in attending the appointment today (tube fare, train fair, petrol, car parking, etc)**

Total travel cost £_____

5. **Did you incur any other expenses in attending the appointment today for example child care costs/needing to do overtime to make up work time? (Please specify type of cost and cost incurred)**

Type of cost(s) _____ Amount incurred (£) _____

6. **Has anyone accompanied you on your visit today?**

(a) Yes ☐

(b) No ☐

I am now going to ask you some questions concerning two tests you may have had at the diabetes clinic.

They are:

Test 1	Purpose
Random blood glucose test	Fingerprick test to measure your blood sugar level at certain times. This is similar to the test you may carry out yourself

7. **Did you have your blood sugar taken at the last diabetes clinic?**

(a) Yes ☐

(b) No ☐

(c) Don't know ☐

8. **Were you told the result of the blood sugar test?**

(a) Yes ☐

(b) No ☐

(c) Don't know ☐

I now want to ask you about <u>another test</u> that you may have had at the diabetes clinic.

Test 2	Purpose
HbA_{1C}	A blood test which measures the level of diabetic control over the previous 6–8 weeks

9. Did you <u>have this test taken</u> at the last diabetes clinic?

(a) Yes ☐ **Go to question 10**

(b) No ☐ **Go to question 15**

(c) Don't know ☐ **Go to question 15**

10. How did you receive the result of this test for HbA_{1C} (measure of long-term control)?
(Please specify the most appropriate response)

(a) At the **same** clinic that I had the test ☐ **Go to question 13**

(b) At the next clinic visit ☐ **Go to question 12**

(c) I had to make an additional clinic visit ☐ **Go to question 11**

(d) By post ☐ **Go to question 12**

(e) I did not receive the result ☐ **Go to question 15**

(f) Other (please specify, e.g. tested at Peter Bishop ward) _____

11. If you have answered (c) to the previous question, were the costs to you of this extra clinic visit similar to the costs to you of visiting the clinic today?

(a) Yes ☐

(b) No ☐

(c) Don't know ☐

12. If you **did not** receive these test results **at the same clinic** as you had the test, how long did you have to wait for the results?

Wait for results _____ days

The next two questions concern the result of the test for long-term control (HbA_{1C}); if you feel <u>either</u> of these questions does not apply, then please miss them out.

13. If you received the result of the test for long-term control (HbA_{1C}) **at the same clinic** as you took the test, how important did you feel that **getting the results straight away was?**

(Please circle the number which corresponds to how important you thought this was, **from 0 if it was not important at all to 5 if you thought it was very important indeed.)**

Not important at all					**Very important indeed**
0	**1**	**2**	**3**	**4**	**5**

14. Please tick the box which shows how much you agree with the following statements.

(i) *Having an immediate feedback of the test result for* ***HbA_{1C}*** *(measure of long-term control) is important to me since it allows me to discuss the implications for my diabetic control with the doctor at the clinic.*

- (a) Agree strongly ☐
- (b) Agree ☐
- (c) Neither agree nor disagree ☐
- (d) Disagree ☐
- (e) Disagree strongly ☐

(ii) *Knowing my* ***HbA_{1C}*** *(**measure of long-term control**) helps me to understand my diabetes.*

- (a) Agree strongly ☐
- (b) Agree ☐
- (c) Neither agree nor disagree ☐
- (d) Disagree ☐
- (e) Disagree strongly ☐

Please would **all respondents** answer questions 15–35.

Please circle a number on each of the scales below to show your level of satisfaction with the following aspects of your diabetes clinic, from 0 if you are very dissatisfied to 5 if you are very satisfied.

15. The amount of time spent talking to the doctor

very dissatisfied 0 1 2 3 4 5 very satisfied

16. The advice given by the doctor

very dissatisfied 0 1 2 3 4 5 very satisfied

17. Continuity of care, that is whether or not you see the same doctor on each visit

very dissatisfied 0 1 2 3 4 5 very satisfied

18. Discussing with the doctor any problems which I might have

very dissatisfied 0 1 2 3 4 5 very satisfied

19. The extent to which I feel understood by the doctor

very dissatisfied 0 1 2 3 4 5 very satisfied

20. Information given to me by the staff regarding my results (e.g. overall diabetes control)

very dissatisfied 0 1 2 3 4 5 very satisfied

21. How I am treated as a person by the staff?

very dissatisfied 0 1 2 3 4 5 very satisfied

22. Time spent waiting at the diabetes clinic

very dissatisfied 0 1 2 3 4 5 very satisfied

23. Please rate how satisfied you are with the overall service provided at the diabetes clinic

very dissatisfied 0 1 2 3 4 5 very satisfied

24. With what (if any) aspects of the service at the diabetes clinic were you dissatisfied?

Please describe

25. How do you think that the service could be improved?

Please describe

26. Do you feel that you understand the importance of maintaining good blood sugar control?

(a) Yes ☐

(b) No ☐

(c) Don't know ☐

27. In your opinion how well controlled is your diabetes now?

(a) Very well ☐

(b) Well ☐

(c) Average ☐

(d) Fair ☐

(e) Poor ☐

In the next section I would like you to answer a few questions concerning your satisfaction with the treatment for your diabetes (including insulin, tablets and/or diet) and your experience over the past few weeks. Please answer each question by circling one number on each of the scales.

28. How satisfied are you with your current treatment?

very dissatisfied	0	1	2	3	4	5	very satisfied

29. How often have you felt that your blood sugars have been unacceptably high recently?

none of the time	0	1	2	3	4	5	most of the time

30. How often have you felt that your blood sugars have been unacceptably low recently?

none of the time	0	1	2	3	4	5	most of the time

31. How convenient have you been finding your treatment recently?

very inconvenient	0	1	2	3	4	5	very convenient

32. How flexible have you been finding your treatment to be recently?

very inflexible	0	1	2	3	4	5	very flexible

33. How satisfied are you with your understanding of your diabetes?

very dissatisfied	0	1	2	3	4	5	very satisfied

34. How satisfied would you be to continue with your present form of treatment?

very dissatisfied	0	1	2	3	4	5	very satisfied

35. Would you recommend this form of treatment to someone else with your kind of diabetes?

No, I would definitely not recommend the treatment	0	1	2	3	4	5	yes, I would definitely recommend the treatment

Finally, please would you fill in the following personal details; again, let me assure you that <u>all the information will be confidential.</u>

Do you take insulin as part of your treatment for diabetes?

Yes ☐

No ☐

To which of these ethnic groups do you belong?

White ☐ Asian ☐

Afro-Caribbean ☐ Other ☐

Sex Male ☐ **Height** ☐ ft ☐ inches or ☐ m ☐ cm

Female ☐ **Weight** ☐ st ☐ lb or ☐ kg

Occupation _____

Partner's occupation (if applicable) _____

If you or your partner are **retired** or **unemployed please would you state your/their most recent occupation**.

I am most grateful for the time you have taken in filling in this questionnaire. Please would you check that you have filled in as much as you can; in particular, make sure you fill in QUESTION 3 relating to appointment/waiting time before you leave today and return the questionnaire to us.

Thank you for your help.

For Office Use Only

Hospital
Hospital no.
Clinic date
HbA_{1c} in clinic today

NEAR PATIENT TESTING FOR DIABETES CARE

Follow-up Questionnaire

I am conducting a study on behalf of the NHS Management Executive to compare the testing facilities at Guy's and St Thomas's diabetes clinics. We would therefore be very grateful if you would answer a few questions concerning your visit today.

1. Please could you estimate the time this particular appointment has involved in **each of the following categories** (where appropriate).

   (a) Waiting time (from your appointment time until you saw the doctor) _____ mins

   (b) Time with doctor _____ mins

   (c) Time taking blood tests _____ mins

   (d) Time with nurse _____ mins

For Office Use Only

Hospital **HbA_{1C}**
Hospital no. **Patient no.**
Clinic date

I am now going to ask you some questions concerning tests you may have had at the diabetes clinic.

They are:

Test 1	Purpose
Random blood glucose test	A test to measure your blood sugar level at a certain time. This is similar to the test you may carry out yourself.

2. Did you have your blood sugar taken at today's diabetes clinic?

(a) Yes ☐
(b) No ☐
(c) Don't know ☐

3. Were you told the result of the blood sugar test?

(a) Yes ☐
(b) No ☐
(c) Don't know ☐

Test 2	Purpose
HbA_{1C}	A test which measures the level of diabetic control over the previous 6–8 weeks

4. Did you have <u>this test taken</u> at today's diabetes clinic?

(a) Yes ☐ **Go to question 5**

(b) No ☐ **Go to question 8**

(c) Don't know ☐ **Go to question 8**

5. Were you told the result(s) of this test for <u>HbA_{1C}</u> (measure of long-term control)?

(a) Yes ☐ **Go to question 6**

(b) No ☐ **Go to question 8**

(c) Don't know ☐ **Go to question 8**

The next three questions concern the result of the test for HbA_{1C} (long-term control); if you feel these questions do not apply to you, then please miss them out.

6. <u>If</u> you were tested for <u>HbA_{1C}</u> (long-term control) in the clinic today and the doctor told you the result, how important do you feel getting the results straight away was?

Please circle the number which corresponds to how important you thought this was, from **0**, **if it was not important at all**, to **5**, **if you thought it was very important indeed**.

Not important at all					**Very important indeed**
0	**1**	**2**	**3**	**4**	**5**

7. Please tick the level of agreement you feel for the following statements.

*(i) Having an immediate feedback of the test result for **HbA_{1C}** (**measure of long-term control**) is important to me since it allows me do discuss the implications for my diabetic control with the doctor at the clinic.*

(a) Agree strongly ☐

(b) Agree ☐

(c) Neither agree nor disagree ☐

(d) Disagree ☐

(e) Disagree strongly ☐

(ii) Knowing my ***HbA*** $_{1C}$ *(**measure of long-term control**) helps me to understand my diabetes.*

(a) Agree strongly ☐

(b) Agree ☐

(c) Neither agree nor disagree ☐

(d) Disagree ☐

(e) Disagree strongly ☐

Test 3	**Purpose**
Cholesterol	Measures the % body fat in the blood and is used to screen for possible heart problems

8. Did you have <u>this test taken</u> at today's diabetes clinic?

(a) Yes ☐ **Go to question 9**

(b) No ☐ **Go to question 11**

(c) Don't know ☐ **Go to question 11**

9. Were you told the result(s) of this test?

(a) Yes ☐ **Go to question 10**

(b) No ☐ **Go to question 11**

(c) Don't know ☐ **Go to question 11**

10. If you were tested for <u>cholesterol</u> in the clinic today <u>and the doctor told you the result</u>, how important do you feel getting the result straight away was?

Please circle the number which corresponds to how important you thought this was, from 0, **if it was not important at all, to 5, if you thought it was very important indeed.**

Not important at all					**Very important indeed**
0	**1**	**2**	**3**	**4**	**5**

Please would **all respondents** answer questions 11–12.

Please circle a number on each of the scales below to show your level of satisfaction with the following aspects of your diabetes clinic/centre.

11. Information given to me by the staff regarding my results (e.g. overall diabetes control).

very dissatisfied 0 1 2 3 4 5 very satisfied

12. Time spent waiting at the diabetes clinic.

very dissatisfied 0 1 2 3 4 5 very satisfied

Please would you write your name below, so we know which patients have been surveyed. The information given by you will be treated as strictly confidential.

Name _____

Please would you leave the questionnaire in the box or return it to me in the envelope provided.

Thank you for your help.

Appendix 3

Breakdown of the different approaches into cost and resource use for the different scenarios considered

Throughout this appendix the numbers reported are rounded to 2 decimal places but, when calculating costs, it is more precise to use 3 decimal places in the actual calculation. For example, if the amount of qualified laboratory time, 0.026 (reported as 0.03) minutes, is multiplied by the price, £9.75, the mean cost is calculated as £0.253 which is then rounded to £0.25.

The average cost per visit of providing each testing service for the base case (scenario A)

TABLE 31 *Conventional testing at Guy's Hospital*

Reagents	**Mean number of tests (SD)**	**Price (£)**	**Mean cost (£) (SD)**
Glucose	1.00 (0.06)	0.73	0.73 (0.04)
HbA_{1C}	0.31 (0.46)	2.38	0.74 (1.09)
Cholesterol	0.21 (0.41)	0.06	0.01 (0.02)
Triglycerides	0.20 (0.40)	0.06	0.01 (0.02)
Creatinine	0.30 (0.46)	0.06	0.02 (0.03)
Total reagent costs			**1.51 (1.21)**
Staff	**Mean time (hours) (SD)**	**Cost (£/hour)**	**Mean cost (£) (SD)**
Testing staff			
Qualified laboratory staff	0.03 (0.04)	9.75	0.25 (0.37)
Phlebotomist	0.14 (0.08)	9.20	1.24 (0.75)
Unqualified nurse	0.00 (0)	4.47	0 (0)
Research nurse	0.00 (0)	9.26	0 (0)
Other staff			
Qualified nurse	0.16 (0)	9.03	1.44 (0.00)
Unqualified nurse	0.54 (0)	4.47	2.41 (0.00)
Unqualified laboratory technician	0.14 (0)	5.93	0.80 (0.02)
Doctor	0.26 (0.14)	23.76	6.08 (3.37)
Total staff costs			**12.24 (4.52)**
Fixed costs	**Mean tests/visit (SD)**	**Unit costs (£)**	**Mean cost (£) (SD)**
Hemocue® (glucose)	1.00 (0.06)	0.05	0.05 (0)
Primus® (HbA_{1C})	0.31 (0.46)	0.64	0.20 (0.29)
Kodak® (lipids, creatinine)	0.71 (1.27)	0.01	0.01 (0.01)
Total fixed costs			**0.26 (0.31)**
Total costs			**14.00 (6.05)**

TABLE 32 *Laboratory NPT at St Thomas's Hospital*

Reagents	**Mean number of tests (SD)**	**Price (£)**	**Mean cost (£) (SD)**
Glucose	1.00 (0.06)	0.05*	0.05 (0)
HbA_{1C}	1.00 (0.06)	2.38	2.38 (0.14)
Cholesterol	0.76 (0.43)	0.06	0.05 (0.03)
Triglycerides	0.75 (0.43)	0.06	0.05 (0.03)
Creatinine	0.75 (0.43)	0.06	0.05 (0.03)
Total reagent costs			**2.57 (0.22)**
Staff	**Mean time (hours) (SD)**	**Cost (£/hour)**	**Mean cost (£) (SD)**
Testing staff			
Qualified laboratory staff	0.18 (0.06)	9.75	1.80 (0.61)
Phlebotomist	0.00 (0)	9.20	0 (0)
Unqualified nurse	0.00 (0)	4.47	0 (0)
Research nurse	0.00 (0)	9.26	0 (0)
Other staff			
Qualified nurse	0.23 (0)	9.03	2.08 (0)
Unqualified nurse	0.23 (0)	4.47	1.03 (0)
Unqualified laboratory technician	0 (0)	5.93	0 (0)
Doctor	0.31 (0.11)	23.76	7.25 (2.52)
Total staff costs			**12.15 (3.13)**
Fixed costs	**Mean tests/visit (SD)**	**Unit costs (£)**	**Mean cost (£) (SD)**
Primus (HbA_{1C})	1.00 (0.06)	0.96	0.96 (0.06)
Kodak (lipids, creatinine, glucose)	3.26 (1.35)	0.65	2.12 (0.88)
Total fixed costs			**3.08 (0.94)**
Total costs			**17.80 (4.28)**

* *Low price because the large number of tests carried out leads to cheaper reagent costs*

TABLE 33 *Nurse NPT at Guy's Hospital*

Reagents	**Mean number of tests (SD)**	**Price (£)**	**Mean cost (£) (SD)**
Glucose	1.00 (0.08)	1.00*	1.00 (0.08)
HbA_{1C}	1.00 (0.06)	3.46	3.46 (0.21)
Cholesterol	1.00 (0.08)	1.58	1.58 (0.13)
Triglycerides	1.00 (0.08)	1.64	1.64 (0.13)
Creatinine	0.68 (0.47)	1.69	1.14 (0.79)
Total reagent costs			**8.82 (1.34)**
Staff	**Mean time (hours) (SD)**	**Cost (£/hour)**	**Mean cost (£) (SD)**
Testing staff			
Qualified laboratory	0 (0)	9.75	0 (0)
Phlebotomist	0.17 (0.01)	9.20	1.53 (0.09)
Unqualified nurse	0.34 (0.02)	4.47	1.52 (0.09)
Research nurse	0.17 (0.01)	9.26	1.54 (0.09)
Other staff			
Qualified nurse	0.16 (0)	9.03	1.44 (0.00)
Unqualified nurse	0.40 (0)	4.47	1.79 (0.00)
Unqualified laboratory technician	0.17 (0.01)	5.93	1.01 (0.06)
Doctor	0.24 (0.12)	23.76	5.70 (2.92)
Total staff costs			**14.54 (3.26)**
Fixed costs	**Mean tests/visit (SD)**	**Unit costs (£)**	**Mean cost (£) (SD)**
DCA 2000 (HbA_{1C})	1.00 (0.06)	0.37	0.37 (0.02)
Spotchem (lipids, creatinine, glucose)	3.68 (0.71)	0.78	2.87 (2.04)
Total fixed costs			**3.24 (2.06)**
Total costs			**26.60 (6.65)**

* *High price because of the small number of tests being performed*

Scenario E: HbA_{1c} results provided by NPT, all others by conventional testing

TABLE 34 *Laboratory NPT*

Reagents	Mean number of tests (SD)	Price (£)	Mean cost (£) (SD)
Glucose	1.00 (0.06)	0.73	0.73 (0.04)
HbA_{1C}	1.00 (0.06)	2.38	2.38 (0.14)
Cholesterol	0.21 (0.41)	0.06	0.01 (0.02)
Triglycerides	0.20 (0.40)	0.06	0.01 (0.02)
Creatinine	0.30 (0.46)	0.06	0.02 (0.03)
Total reagent costs			**3.15 (0.26)**
Staff	**Mean time (hours) (SD)**	**Cost (£/hour)**	**Mean cost (£) (SD)**
Testing staff			
Qualified laboratory	0.11 (0)	9.75	1.09 (0.58)
Phlebotomist	0.12 (0)	9.20	0 (0)
Unqualified nurse	0.12 (0)	4.47	0 (0)
Research nurse	0.00 (0)	9.26	0 (0)
Other staff			
Qualified nurse	0.23 (0)	9.03	2.08 (0)
Unqualified nurse	0.23 (0)	4.47	1.03 (0)
Unqualified laboratory technician	0 (0)	5.93	0 (0)
Doctor	0.31 (0.11)	23.76	7.25 (2.52)
Total staff costs			**11.44 (3.10)**
Fixed costs	**Mean tests/visit (SD)**	**Unit costs (£)**	**Mean cost (£) (SD)**
Hemocue (glucose)	1.00 (0.06)	0.05	0.05
Primus (HbA_{1C})	1.00 (0.06)	0.96	0.96 (0.06)
Kodak (lipids, creatinine)	3.26 (1.35)	0.65	0.02 (0.01)
Total fixed costs			**1.03 (0.07)**
Total costs			**15.62 (3.43)**

TABLE 35 *Nurse NPT*

Reagents	Mean number of tests (SD)	Price (£)	Mean cost (£) (SD)
Glucose	1.00 (0.08)	0.73	0.73 (0.06)
HbA_{1C}	1.00 (0.06)	3.46	3.46 (0.21)
Cholesterol	0.21 (0.41)	0.06	0.01 (0.02)
Triglycerides	0.20 (0.40)	0.06	0.01 (0.02)
Creatinine	0.30 (0.46)	0.06	0.02 (0.03)
Total reagent costs			**4.23 (0.34)**
Staff	**Mean number of hours (SD)**	**Cost (£/hour)**	**Mean cost (£) (SD)**
Testing staff			
Qualified laboratory	0.03 (0.06)	9.75	0.24 (0.60)
Phlebotomist	0.17 (0.01)	9.20	1.53 (0.09)
Unqualified nurse	0.34 (0.02)	4.47	1.52 (0.09)
Research nurse	0 (0)	9.26	0 (0)
Other staff			
Qualified nurse	0.16 (0)	9.03	1.44 (0.00)
Unqualified nurse	0.40 (0)	4.47	1.79 (0.00)
Unqualified laboratory technician	0.17 (0.01)	5.93	1.01 (0.06)
Doctor	0.24 (0.12)	23.76	5.70 (2.92)
Total staff costs			**13.24 (3.76)**
Fixed costs	**Mean tests/visit (SD)**	**Unit costs (£)**	**Mean costs (£) (SD)**
Hemocue (glucose)	1.00 (0.06)	0.05	0.05 (0)
DCA 2000 (HbA_{1C})	1.00 (0.06)	0.37	0.37 (0.02)
Kodak (lipids, creatinine)	1.71 (1.35)	0.01	0.02 (0.02
Total fixed costs			**0.44 (0.55)**
Total costs			**17.91 (4.15)**

Low volume of patients (Scenario F)

TABLE 36 *Conventional testing at Kent and Sussex Hospital (modelled)*

Reagents	Mean number of tests (SD)	Price (£)	Mean cost (£) (SD)
Glucose	1.00 (0.06)	0.73	0.73 (0.04)
HbA_{1C}	0.31 (0.46)	2.38	0.74 (1.09)
Cholesterol	0.21 (0.41)	0.06	0.01 (0.02)
Triglycerides	0.20 (0.40)	0.06	0.01 (0.02)
Creatinine	0.30 (0.46)	0.06	0.02 (0.03)
Total reagent costs			**1.51 (1.21)**
Staff	**Mean time (hours) (SD)**	**Cost (£/hour)**	**Mean cost (£) (SD)**
Testing staff			
Qualified laboratory	0.03 (0.04)	9.75	0.25 (0.37)
Phlebotomist	0.14 (0.08)	9.20	1.24 (0.75)
Unqualified nurse	0.14 (0)	4.47	0.63 (0)
Research nurse	0.00 (0)	9.26	0 (0)
Other staff			
Qualified nurse	0.28 (0)	9.03	2.53 (0)
Unqualified nurse	0 (0)	4.47	0 (0)
Unqualified laboratory technician	0 (0)	5.93	0 (0)
Doctor	0.35 (0)	23.76	8.32 (0)
Total staff costs			**12.96 (1.15)**
Fixed costs	**Mean tests/visit (SD)**	**Unit costs (£)**	**Mean cost (£) (SD)**
Hemocue (glucose)	1.00 (0.06)	0.05	0.05 (0)
Primus (HbA_{1C})	0.31 (0.46)	0.64	0.20 (0.29)
Kodak (lipids, creatinine)	0.71 (1.27)	0.01	0.01 (0.01)
Total fixed costs			**0.26 (0.31)**
Total costs			**14.73 (2.67)**

TABLE 37 *Laboratory NPT at Kent and Sussex Hospital (modelled)*[*]

Reagents	Mean number of tests (SD)	Price (£)	Mean cost (£) (SD)
Glucose	1.00 (0.06)	0.73	0.73 (0.04)
HbA_{1C}	1.00 (0.06)	2.38	2.38 (0.14)
Cholesterol	0.21 (0.41)	0.06	0.01 (0.02)
Triglycerides	0.20 (0.40)	0.06	0.01 (0.02)
Creatinine	0.30 (0.46)	0.06	0.02 (0.03)
Total reagent costs			**3.15 (0.26)**
Staff	**Mean time (hours) (SD)**	**Cost (£/hour)**	**Mean cost (£) (SD)**
Testing staff			
Qualified laboratory	0.45 (0.06)	9.75	4.36 (0.58)
Phlebotomist	0.14 (0.02)	9.20	1.24 (0)
Unqualified nurse	0.14 (0)	4.47	0.63 (0)
Research nurse	0.00 (0)	9.26	0 (0)
Other staff			
Qualified nurse	0.24 (0)	9.03	2.53 (0)
Unqualified nurse	0 (0)	4.47	0 (0)
Unqualified laboratory technician	0 (0)	5.93	0 (0)
Doctor	0.35 (0)	23.76	8.32 (0)
Total staff costs			**17.08 (0.58)**
Fixed costs	**Mean tests/visit (SD)**	**Unit costs (£)**	**Mean cost (£) (SD)**
Hemocue (glucose)	1.00 (0.05)	0.05	0.05 (0)
Primus (HbA_{1C})	1.00 (0.06)	3.81	3.81 (0.23)
Kodak (lipids, creatinine)	1.71 (1.33)	0.01	0.02 (0.01)
Total fixed costs			**3.88 (0.24)**
Total costs			**24.11 (1.09)**

[*] *HbA_{1C} results by laboratory NPT and other results by conventional testing*

TABLE 38 *Nurse NPT at Kent and Sussex Hospital (modelled)*

Reagents	**Mean number of tests (SD)**	**Price (£)**	**Mean cost (£) (SD)**
Glucose	1.00 (0.08)	0.73	0.73 (0.06)
HbA_{1C}	1.00 (0.06)	3.46	3.46 (0.21)
Cholesterol	0.21 (0.41)	0.06	0.01 (0.02)
Triglycerides	0.20 (0.40)	0.06	0.01 (0.02)
Creatinine	0.30 (0.46)	0.06	0.02 (0.03)
Total reagent costs			**4.37 (2.35)**
Staff	**Mean time (hours) (SD)**	**Cost (£/hour)**	**Mean cost (£) (SD)**
Testing staff			
Phlebotomist	0.14 (0.02)	9.20	1.24 (0.15)
Unqualified nurse	0.14 (0)	4.47	0.63 (0)
Research nurse	0 (0)	9.26	0 (0)
Other staff			
Qualified nurse	0.28 (0)	9.03	2.53 (0)
Unqualified nurse	0 (0)	4.47	0 (0)
Unqualified laboratory technician	0 (0)	5.93	0 (0)
Doctor	0.35 (0)	23.76	8.32 (0)
Total staff costs			**12.96 (0.76)**
Fixed costs	**Mean tests/visit (SD)**	**Unit costs (£)**	**Mean cost (£) (SD)**
Hemocue (glucose)	1.00 (0.05)	0.05	0.05 (0)
DCA 2000 (HbA_{1C})	1.00 (0.06)	0.37	0.37 (0.02)
Kodak (lipids, creatinine)	1.71 (1.33)	0.01	0.02 (0.02)
Total fixed costs			**0.44 (0.04)**
Total costs			**17.76 (3.16)**

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This report was identified as a priority by the Diagnostics and Imaging Panel.

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Copies of this report can be obtained from:

The National Coordinating Centre for Health Technology Assessment,
Mailpoint 728, Boldrewood,
University of Southampton,
Southampton, SO16 7PX, UK.
Fax: +44 (0) 1703 595 639 Email: hta@soton.ac.uk
http://www.hta.nhsweb.nhs.uk

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