Health Technology Assessment 2000; Vol. 4: No. 11

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Health Technology Assessment
NHS R&D HTA Programme

Standing Group on Health Technology

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Cost and outcome implications of the organisation of vascular services

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Competing interests: none declared

Published June 2000

This report should be referenced as follows:

Michaels J, Brazier J, Palfreyman S, Shackley P, Slack R. Cost and outcome implications of the organisation of vascular services. *Health Technol Assess* 2000;**4**(11).

Health Technology Assessment is indexed in *Index Medicus*/MEDLINE and *Excerpta Medica*/EMBASE. Copies of the Executive Summaries are available from the NCCHTA website (see overleaf).

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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 Acute Sector Panel and funded as project number 94/20/01.

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.

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Series Editors: Andrew Stevens, Ruairidh Milne, Ken Stein and John Gabbay
Monograph Editorial Manager: Melanie Corris

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.

ISSN 1366-5278

Published by Core Research, Alton, on behalf of the NCCHTA.
Printed on acid-free paper in the UK by The Basingstoke Press, Basingstoke.

Copies of this report can be obtained from:

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List of abbreviations

AAA	abdominal aortic aneurysm
ABPI	ankle/brachial pressure index
ALI	acute limb ischaemia*
BMJ	British Medical Journal
CE	carotid endarterectomy
CI	confidence interval
CNDRH	Chesterfield and North Derbyshire Royal Hospital
CRD	Centre for Reviews and Dissemination
CT	computed tomography*
CVA	cerebrovascular accident*
DGH	district general hospital
ECG	electrocardiogram*
FCE	finished consultant episode
HDU	high-dependency unit
HRG	healthcare resource group
ICD	International Classification of Diseases
ITT	intention to treat
ITU	intensive therapy unit
MI	myocardial infarction*
MUGA	multiple-gated arteriography*
NGH	Northern General Hospital
NNB	number needed to benefit
NNH	number needed to harm
OPCS	Office of Population Censuses and Surveys
PAOD	peripheral arterial occlusive disease*
PTA	percutaneous transluminal angioplasty
PVD	peripheral vascular disease
QALY	quality-adjusted life year
QoL	quality of life
RCT	randomised controlled trial
RR	relative risk
rt-PA	recombinant tissue plasminogen activator
SD	standard deviation
STILE	Surgery versus Thrombolysis for Ischaemia of the Lower Extremity (study)
TIA	transient ischaemic attack*
TOPAS	Thrombolysis or Peripheral Arterial Surgery (study)

* Used only in tables

Executive summary

Objectives

To evaluate the cost and quality implications of different possible organisational models for sub-specialist vascular services.

Design

A number of techniques were used including local activity analysis, systematic literature review, conjoint analysis, utility analysis using a standard gamble technique, decision analysis and modelling.

Setting

The study was based upon the population requiring vascular services in North Trent, comprising Sheffield and the surrounding health districts.

Subjects

Activity data related to users of vascular services in North Trent. For conjoint analysis, an outpatient sample of patients with moderate or mild peripheral vascular disease in a teaching and a district general hospital in North Trent was used. For the standard gamble exercise a sample of the general population was identified in four districts within North Trent.

Interventions

All vascular surgical and interventional radiological procedures carried out for patients with vascular disease were considered in the workload analysis and modelling exercise. A number of options for the organisation of services were considered including devolved, fully centralised and 'hub and spoke' arrangements. Utility analysis used a 'no props' variant of the standard gamble technique. Conjoint analysis was through a self-completed postal questionnaire.

Main outcome measures

The study considered clinical outcomes including mortality, amputation and symptom severity, generic outcomes of utility, quality-adjusted life years (QALYs) and patient preference, resource use, costs and cost-effectiveness.

Results

Data analysis showed significant differences between districts in terms of the services on offer, rates of procedures and possible indicators of outcome. Key issues that were identified were the relationship between volume and outcome for particular procedures, access to carotid endarterectomy, differences in the availability and use of femoro-distal bypass and endovascular treatments, and differences in some outcome measures including mortality and rates of major amputation. The findings of local activity analysis were supported by those of the literature reviews.

The effect of different treatments for peripheral vascular disease on QALY was estimated. Conjoint analysis showed a strong preference for the availability of local treatment. Modelling demonstrated that centralisation of services would be expected to lead to improved outcomes but with an increase in overall resource requirements, and the cost-effectiveness of some of the changes was estimated.

Conclusions

The study has demonstrated a number of problems stemming from the current configuration of vascular services, which are leading to excess mortality and morbidity, including limb loss and stroke. There is a need to rationalise services, taking into account the demonstrated clinical benefits of sub-specialisation and patient preferences for local services. The compromise of 'hub and spoke' arrangements, with a variable range of facilities being provided locally through a service linked to a major centre would seem likely to best achieve this compromise for centres without sufficient workload to provide a full range of local services. Such an arrangement would also be relatively straightforward to achieve through a staged reconfiguration of services.

Further research is required to allow better identification of casemix and outcome through coding systems, to study the cost-effectiveness of both established and new vascular interventions, to consider the issues around access to services and the determinants of patient preferences.

Chapter 1
Background

Increasing sub-specialisation has produced considerable organisational problems in many specialities. Over the past 20 years general surgery has gradually developed a number of sub-specialities, with some of these already being recognised as separate entities with their own training and accreditation. Urology became a separate speciality some years ago and other components of general surgery are moving in the same direction.[1]

Vascular surgery is a relatively new speciality. In the UK the Vascular Surgical Society was formed in 1966 with 26 members and has expanded to a membership of 626 in 1998.[2] Recent developments in both surgical and radiological techniques have led to a rapid growth in the sub-specialities of both vascular surgery and vascular radiology.[3,4] This process has led to considerable organisational problems in the provision of vascular services in many countries.[5,6]

Vascular surgery presents particular problems in that much of the workload is complex and urgent, it may require technology that is specialised and expensive and frequently requires the involvement of a multidisciplinary team.[7] In most countries vascular surgical services have developed gradually out of general surgical services without any pro-active planning. This may have resulted in the development of a suboptimal service. There are a number of conflicting pressures that need to be considered when determining the optimum strategy for the delivery of vascular services.[5]

- It is generally assumed that greater specialisation produces improved outcomes and this has led to various changes within other sub-specialities of general surgery, for example cancer services.[8] However, the published evidence needs to be fully evaluated in the light of possible differences in casemix. It is necessary to know the volumes of particular procedures that must be carried out by a single centre or surgeon to generate any benefit, and the magnitude of such a benefit needs to be quantified.
- There are many considerations concerning access to services, which may be influenced by the configuration of services.
- There are a number of cost issues, particularly surrounding the provision of specialised high technology equipment and services, which may be under-utilised in small units.
- The linkages of vascular surgery to other specialities need to be carefully considered. This applies both in terms of the specialised support services that patients undergoing vascular procedures may require and also in terms of the input that is required from vascular specialists to the management of patients under the care of other departments.
- Consideration needs to be given to the extent to which the configuration of services affects its ability to provide adequate training, research and development.
- The recent White Paper[9] has focused attention on clinical governance and there is a need for health service providers to be in a position to maintain a high-quality service and assess the performance of individual practitioners.
- A large part of the workload of vascular services is of an urgent or emergency nature[10] and the advantages of rapid access to the locally available treatment need to be weighed against the potential for treatment in a larger centre with more specialist support.

Aims and objectives

The overall aim of the project was to evaluate the cost and quality implications of different possible organisational models for sub-specialist vascular services. In order to achieve this aim there are a number of objectives that need to be met.

- To assess the current workload, casemix and referral patterns relating to patients with vascular disease.
- To identify differences in management between centres and to assess how these are likely to be altered by changes in models of care.
- To collect cost and resource usage data and relate these to workload and organisation structure.
- To estimate the expected outcomes of vascular interventions and relate these to workload and organisational structure.

- To estimate the utility attached to relevant clinical outcomes to enable these to be synthesised into a single cost–utility model where appropriate.
- To evaluate patient preferences for various aspects of the services, which may be related to organisational structure.
- To characterise the possible models for the delivery of vascular services.
- To integrate all the information into an operational model that will allow different organisational structures to be assessed in terms of their implications for cost and outcome.

Overview

In order to achieve the stated objectives the project has studied a large number of different issues using a variety of techniques. The project has focused upon the organisation of services in the area around the City of Sheffield to address the issues that require specific local data. Wider issues have been dealt with through literature reviews and economic modelling. The local issues are thought to be typical of those that arise in other areas of the UK and elsewhere.

There are a number of components of the project, which are all related to the organisation of vascular services and include the following.

- Assessment of the current managerial arrangements for the vascular services.
- Analysis of the current levels, casemix and possible changes in pattern of workload.
- Analysis of the relationship between outcome and configuration of services.
- Consideration of patient preferences in so far as they relate to service provision.
- Estimation of cost and resource use.
- Economic modelling to predict the effect of possible reconfiguration of services on resource use, costs and outcomes.
- Discussion and conclusions regarding the implications of the finding and other related issues such as the effect of configuration of services on new developments, research and training.

These are discussed below and in the following chapters of this report.

Current vascular services

The current organisation of the vascular services has been established in terms of the arrangements that are in place for patients requiring access to such services.

The local arrangements have been evaluated through a process of consultant interviews and questionnaires at each of the hospitals in North Trent. These addressed both the surgical and radiological services that are provided to patients with vascular conditions. The available resources, both in terms of equipment and personnel, have been identified, as have any protocols or management practices that govern the provision of services.

Workload

An analysis of the vascular workload in North Trent has been carried out based primarily on routinely collected data. This included definition of the main casemix groups treated by vascular specialists, followed by an analysis of the workload throughout North Trent. This analysis included a number of aspects of the service.

- The rates of admission related to particular diagnostic or casemix categories.
- Differences in the rates of particular procedures carried out.
- Evidence of differences in casemix that is available from routinely collected data. For example, diagnostic age and gender groupings.
- An analysis of current cross-boundary flows for particular procedures or diagnostic groups.

This description of the workload in North Trent has been supplemented by a review of published evidence regarding systematic differences in practice, between different hospital settings.

Outcomes

The outcomes of vascular services have been characterised in as far as they are likely to be affected by the reconfiguration of services.

Outcome measures that are available from routinely collected data have been identified and analysed for the dataset for North Trent. The usefulness of these measures has been assessed in regard to their possible use as performance indicators.

Review of the literature has been carried out to establish the extent to which differences in the configuration of service are likely to lead to differences in outcome. This includes an analysis of any systematic differences that are expected in access to service, availability of particular procedures or pathways of care and the relationship between volume of individual practitioners or centres and outcome.

Patient preferences

Patient preferences are relevant to the reconfiguration of services in two main ways. First, the value that patients ascribe to specific outcomes or conditions is a determinant of the degree of benefit that may be achieved by different treatments or configurations that will affect those outcomes. Thus, an exercise has been carried out to obtain the values or utilities that patients ascribe to some outcomes relevant to vascular disease, in order to use these in a model of the management of peripheral vascular disease (PVD).

The second aspect of patient preferences that needs to be considered is the strength of preference for other aspects of the services, such as location, travelling and waiting times. These have been evaluated through the use of a technique known as conjoint analysis. Staff and patients have identified key issues of possible relevance to the organisation of services and an analysis has been carried out to determine the strength of preference that patients have for the different aspects of the service.

Costs

The North Trent data have been used to identify differences in the resource use in terms of length of stay and procedures in the different casemix categories. These have been combined with more detailed costing of individual procedures in order to look at the main cost drivers, such as theatre usage, consumables and length of stay.

The information collected locally has been supplemented by a systematic literature review to collect and collate any published evidence regarding the costs of vascular services.

Operational modelling

Based upon the local data collected in North Trent, a computer model has been developed to predict the effect of different scenarios for care upon workload, casemix and resource use.

The possible scenarios for service provision have been outlined based upon the current arrangements in North Trent and a review of published evidence. Further detailed consideration has been given to the effect of suggested arrangements on specific casemix groups.

The implication of any differences in terms of expected differences in outcome, have been discussed, along with economic evaluation, where appropriate, to evaluate the cost and outcome implications associated with specific issues.

Discussion and conclusions

The results of the above aspects of the study have been drawn together in assessing the overall implications of the findings for the configuration and provision of vascular services both locally and on a wider scale. Along with this there has been further consideration of other related issues, such as the possible means for managing any necessary changes and the effect of service development, research and teaching.

The evidence collected through this study has been correlated with a variety of evidence from other sources in order to draw up some evidence-based guidelines for the provision of vascular services and these have been included as an appendix and discussed in the text.

A number of recommendations have also been made regarding the needs for further research that have been identified during this study.

Chapter 2

Current vascular services

For the purposes of this report the modelling concentrates on the arrangements for the provision of vascular services within Sheffield and the surrounding districts.

Demographics

The populations for these districts for mid-year 1996 are shown in *Table 1*.[11] Unfortunately it has not been possible to separately identify data relating to the population served by Bassetlaw Hospital. Estimates for the workload for the relevant population have been based upon the average for North Nottinghamshire, assuming that Bassetlaw serves a population of 105,000.

TABLE 1 *Populations of district in North Trent. Mid-1996 estimates from OPCS data.*[11]

	Population (1000s)
Barnsley	226.28
Doncaster	295.32
North Derbyshire	377.16
Worksop	105*
Rotherham	256.56
Sheffield	527.25
Total	**1787.57**

**Based on local estimate*

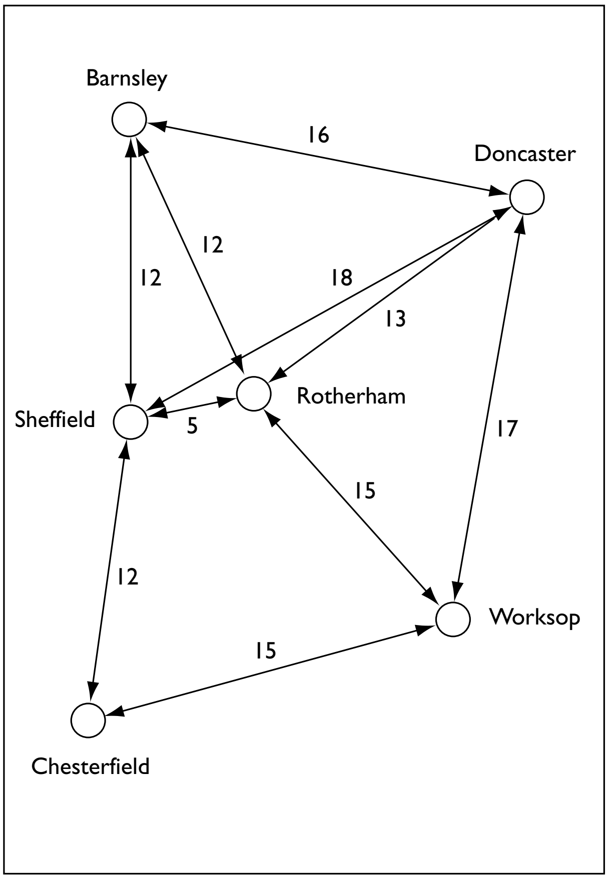

FIGURE 1 *Sheffield and the surrounding districts showing distances by road (miles) between major hospitals in each district*

Figure 1 shows a map of the districts in question with the distances by road between the major centres of population. It is evident that North Trent has a large urban population within a fairly small area, the only exception to this is the North Derbyshire district, which has a sizeable rural population.

Although there are no reliable published data on the prevalence of PVD, the population served would be expected to have a fairly high incidence of PVD, compared with the general population of the UK. Demographic information about the region shows the following features.

- It is a relatively deprived area. Based on the Townsend index, the four metropolitan districts of South Yorkshire have the highest Townsend Score within Trent, which in itself is high compared with the general population.[12]
- In terms of age-mix the 1991 census showed that 6.8% of the population of Trent are over the age of 75 years. This figure is fairly static, though the proportion of those over 85 years is gradually increasing, with 75% of the over 85 years group being women.[13]
- The rate of smokers within Trent is in line with the national average, the overall rate of adult smokers being 27% but some areas have a significantly higher proportion, such as Doncaster at 31%.[14]
- There is significant variation in the incidence of obesity, Trent having the highest average

body mass index in the UK. It is estimated that approximately 33% of females and 44% of males in Trent are overweight and 18% and 15% respectively are obese.[15]

In looking at some of the general health indicators, it is likely that PVD will quite closely follow the trends for coronary heart disease and stroke. In both these areas the Trent region has a high standardised mortality rate, though over the past 10 years this has been gradually decreasing.[16,17] There is variation within Trent and some of the districts in question have particularly high rates. For example, the standardised mortality rate in Rotherham for coronary heart disease in the under 73 years age group is 132, and in Barnsley it is 115, and for stroke the rates are 123 for both Barnsley and Rotherham.

A recent study of the use of cardiology services showed that many areas in the Trent region have an incidence of coronary heart disease, as marked by angina, that is well above the national average. This was associated with areas of deprivation as judged by the Townsend score and in these areas patients tend to have a lower access to coronary revascularisation.[18]

Participating districts

The current study is based upon the organisation of services in the North Trent area. This comprises the hospitals in the districts of Sheffield, Rotherham, Barnsley, Doncaster, North Derbyshire and part of North Nottinghamshire. At the start of the study Sheffield was receiving significant referrals from Huddersfield and Dewsbury, and these centres participated in some of the parts of the study. However, the total number of referrals was small and has subsequently decreased, full workload data were not available and these centres are not in the Trent region. They have, therefore, been excluded from the detailed modelling.

Throughout the text of this report, the term 'North Trent' is used to refer to the six districts as described below, while the term 'Trent' is used to refer to the entire Trent health region.

Sheffield

Sheffield is a large teaching district with two main hospitals within the city. The immediate population of the district is approximately 530,000 (all population estimates are based upon estimates for mid-1996 from the Office of Population Censuses and Surveys (OPCS)).

The vascular services were reorganised as part of an ongoing reorganisation of acute services within the city. The two major teaching hospitals both provide an acute general surgical service. Prior to 1995 separate vascular services were provided at both the Royal Hallamshire Hospital and the Northern General Hospital (NGH). As part of the acute services review a specification was drawn up with Sheffield Health Authority for vascular services for the Sheffield district and the service was centralised on 1 October 1995. The Sheffield Vascular Institute was formed at the NGH with the amalgamation of the services from the Royal Hallamshire and the NGH.

Vascular inpatient facilities were centralised at the NGH but outpatient clinics, day-case surgery lists, diagnostic radiology and emergency cover continue to be provided at the Royal Hallamshire Hospital. The Sheffield Vascular Institute provides a full emergency rota, with the availability of a vascular surgeon and radiologist separate from the general surgery rota. Junior staff on-call cover both general and vascular surgery. In addition to the surgical services, specialist vascular nursing services have been developed, with several clinical nurse specialists and the provision of nurse-led outpatient services.

Rotherham

Rotherham District General Hospital provides the local services for a population of approximately 260,000. There are a total of five general surgical consultants, two having a vascular interest. There are four radiologists one with a particular vascular interest. The centre of the Rotherham District is situated approximately 7 miles from the NGH and some elective and emergency referrals go directly to the Sheffield district. There has also been an informal arrangement for tertiary referral of elective cases (particularly complex radiological cases) and for emergency surgical referrals, if a vascular surgeon was not available. This arrangement was formalised as from April 1996, the arrangement being that the surgeons with a vascular interest continue to take part in the general surgical on-call, and on those nights when they are not available, vascular emergencies are redirected to Sheffield.

Chesterfield

Chesterfield District General Hospital provides acute services to North Derbyshire, covering a mainly rural population of approximately 377,000. The centre of Chesterfield is approximately 11 miles from Sheffield. Over the period to which the data relate there have been five surgeons, one of whom has a major vascular interest and a single radiologist with a vascular interest. There has subsequently been an appointment of a further general surgeon, with a vascular interest. Chesterfield has no separate arrangements for emergency vascular surgery with vascular surgery being dealt with by the general surgeon on-call and an *ad hoc* arrangement for both emergency and tertiary referrals to Sheffield when considered necessary.

Barnsley

Barnsley District General Hospital services a population of approximately 226,000. The centre of the district is approximately 14 miles from the NGH. The hospital currently has five general surgeons, one of whom has a major vascular interest and one radiologist with a major vascular interest. There are no formal arrangements for emergency vascular surgery and both elective and emergency vascular cases are transferred to Sheffield when considered to be clinically appropriate.

Worksop

Bassetlaw Hospital in Worksop provides part of the service for North Nottinghamshire, which has a population of approximately 390,000. The catchment population for Bassetlaw Hospital is approximately 105,000 and it has a small acute surgical service, with three consultant surgeons, none of whom have a vascular interest. Sheffield has provided the vascular service for Bassetlaw for several years. There is a monthly out-reach clinic (recently increased to bimonthly) carried out by the vascular surgeons from Sheffield and all major elective surgical and radiological procedures are carried out in Sheffield. There is an emergency general surgical rota but vascular cases are transferred to Sheffield.

The centre of Worksop is approximately 15 miles from Sheffield and a similar distance from Doncaster.

Doncaster

Doncaster General Hospital serves the population of approximately 295,000. They currently have nine general surgeons, three of whom have a vascular interest. The vascular surgeons currently take part in the general surgical rota but also offer an emergency vascular surgical on-call rota. Two of the radiologists have a vascular interest but no separate emergency vascular radiological service is offered.

Survey of participating districts

The initial analysis of the local arrangements regarding vascular services was carried out through a questionnaire of consultants and requests for information from hospital managers.

A questionnaire to determine the casemix and decisions made regarding treatment was undertaken between May 1996 and May 1997. The total number of surgeons with a vascular practice in the seven local hospitals (including Huddersfield and Dewsbury) was 13. Results are presented on the ten (in six hospitals) who participated in the study. One refused to participate and the other two were unavailable for interview. The information obtained via the questionnaire was validated by reference to local information where available.

To maintain confidentiality the hospitals and consultants have been allocated a code number. The coded participants and settings in which they work are shown in *Table 2*.

Vascular services and facilities available

A summary of the vascular practice of the surgeons and facilities available to them is presented in *Table 3*. Hospital A was the only hospital where there were surgeons specialising purely in vascular surgery. Of the four vascular consultants, three spent 100% of their time on vascular services and one spent 10% of his time on transplant procedures.

Surgeons B1 and E1 at Hospitals B and E, respectively, spent 70% of their time on vascular surgery with the remainder on general surgery. The other surgeons interviewed reported that they split their time equally between vascular surgery and general surgery. The exception was surgeon C1 who only spent 30% of his time on vascular work.

All of the hospitals had an intensive therapy unit (ITU) but only two had a high-dependency unit (HDU). The ITU was used at all the hospitals for emergency surgical patients, particularly abdominal aortic aneurysm (AAA) repair. In those hospitals with an HDU the more complex elective surgery, such as elective AAA repair and carotid endarterectomy (CE), tended to go the HDU rather than the ITU.

The lack of an HDU was reported to have had an impact on the workload, with consultants at three out of four hospitals reporting that they had to cancel elective operations on a ‘regular basis’ due to insufficient ITU beds. Even where there were HDU facilities available, the consultants still reported problems with cancellation of elective operations due to no ITU or HDU beds.

***TABLE 2** Description of hospitals and vascular service provided by participants in questionnaire survey*

Hospital	Consultant code	Interviewed	Description of vascular service provided
A	A1 A2 A3 A4	Yes Yes Yes Yes	Large teaching hospital with specialised vascular unit
B	B1 B2 B3	Yes Yes No	Medium-sized hospital with three consultants performing vascular surgery
C	C1 C2	Yes No	DGH with two consultants performing vascular surgery
D	D1	Yes	DGH with single vascular consultant and a general surgeon who does emergency vascular work
E	E1	Yes	DGH with single vascular consultant
F	F1	Yes	DGH with single vascular consultant
G	G1	No	Declined

DGH, district general hospital

***TABLE 3** Description of services available and vascular provision reported by participants in questionnaire survey*

Hospital	Consultant code	% Time on vascular	Other speciality	On-call rota	ITU	HDU	Vascular laboratory
A	A1 A2 A3 A4	100 100 100 90	N/A N/A N/A Transplant surgery	Yes	Yes	Yes	Yes
B	B1 B2	70 50	General surgery General surgery	Yes	Yes	Yes	Yes
C	C1	30	General surgery	No	Yes	No	Yes
D	D1	60	General surgery	Yes	Yes	No	Yes
E	E1	70	General surgery	No	Yes	No	No
F	F1	50	General surgery	No	Yes	No	Yes

N/A, not applicable

All but one of the hospitals had a dedicated vascular laboratory and vascular radiologists or radiologists with an interest in interventional vascular radiology. The exception was Hospital E where there was no vascular laboratory or vascular radiologist.

There was a 24-hour on-call vascular surgical service at two hospitals (A and B), with a 24-hour on-call vascular radiological service at Hospital A. Hospital D provided an on-call rota for 5 days a week with vascular referrals being transferred to another centre on the other 2 days. The remaining hospitals (C, E and F) did not have formal arrangements for an out-of-hours emergency vascular service and the general surgical consultant on-call would call the local specialist or refer to a larger centre on an *ad hoc* basis.

Elective AAA repair

There was some variation in the surgeons' treatment criteria (*Table 4*). Seven out of ten consultants had no upper age limit and assessed individual patients for their suitability for the

TABLE 4 *Description of practice as regards aortic aneurysm repair reported by participants in questionnaire survey*

Hospital	Consultant code	Investigation	Preoperative admission	Postoperative stay	Length of stay (days)	Follow-up
A	A1	Echocardiogram, ultrasound, CT, angiogram, MUGA	1 day	HDU	7–10	1–2 years
	A2	Echocardiogram, ultrasound, MUGA, CT				Life
	A3	Echocardiogram, ultrasound, MUGA, 24-hour ECG				1 year
	A4	Echocardiogram, ultrasound, MUGA, CT, angiogram				1 year
B	B1	Echocardiogram, CT, ultrasound	1 day or same day	HDU	10	1–2 years
	B2	Echocardiogram, MUGA or CT, ultrasound			6	Once only at 6 weeks
C	C1	Echocardiogram, ultrasound	1 day	ITU	≥ 10	1–2 years
D	D1	Echocardiogram, ultrasound	2 days	ITU	14	2 years
E	E1	Echocardiogram, ultrasound, CT	2 days	ITU	10	5 years
F	F1	24-hour ECG, ultrasound	1 day	ITU	7	Life

CT, computed tomography; MUGA, multiple-gated arteriography; ECG, electrocardiogram

operation. The other three had an upper age limit of greater than 80 years and applied the same age limit to emergency surgery.

The minimum size of aneurysm that would be considered for surgery varied from 4.5 cm to 6 cm, though it should be noted that the results of the small aneurysm trial[19] had not been published at the time of the interviews and some of the centres were participating in this trial.

The number and range of preoperative investigations patients underwent was greatest at Hospital A and included angiography, multiple-gated arteriography scan (for cardiac output), computed tomography, ultrasound and respiratory function. At the other hospitals the most common investigations were echocardiogram and ultrasound. Some of the reason for this variation could be accounted for by trial protocols that were in force at the time of the questionnaire.

The majority of the hospitals (four out of six) had some form of preoperative assessment clinic, which allowed them to reduce the need for preoperative stay for investigations. Two hospitals (D and E) did not have preoperative assessment and the policy in both was to admit the patients 2 days prior to the operation.

Postoperatively the patients were routinely admitted to HDU in the two hospitals where this was available (A and B), otherwise they were admitted to ITU.

The planned length of stay ranged from 7 to 14 days with the two largest centres reporting lower planned lengths of stay than the smaller ones.

The follow-up period after discharge was usually for 1–2 years. The exceptions to this were A2 and F1 who followed-up for life, and E1 who followed the patients for 5 years.

The only centre where endovascular treatment options were available was Hospital A. The other hospitals transferred some patients to Hospital A for endovascular procedures.

CE

This treatment was not available at two of the hospitals (C and F) and only one surgeon at Hospital B (B2) performed this operation. Where the service was not available patients were screened and referred to another centre (usually Hospital A). The policies with respect to the procedure are shown in *Table 5*.

There appeared to be a general consensus on the treatment criteria with all the consultants

***TABLE 5** Description of practice as regards carotid surgery reported by participants in questionnaire survey*

Hospital	Consultant code	Treatment criteria	Investigations	Postoperative stay	Follow-up
A	A1	> 70% stenosis, TIA, CVA, amaurosis fugax	Assessed by neurologist; angiography, duplex, CT scan	HDU	1 year
	A2				3 months
	A3				1 year
	A4				1 year
B	B1	N/A	N/A	N/A	N/A
	B2	> 70% stenosis, TIA, CVA, amaurosis fugax	Angiography, duplex, CT scan	HDU	6 weeks
C	C1	N/A	N/A	N/A	N/A
D	D1	> 70% stenosis, TIA, CVA, amaurosis fugax	Angiography, duplex, CT scan	Ward	6 months
E	E1	> 70% stenosis, TIA, CVA, amaurosis fugax	Angiography, duplex, CT scan	ITU	5 years
F	F1	N/A	N/A	N/A	N/A

TIA, transient ischaemic attack; CVA, cerebrovascular accident

treating patients with greater than 70% stenosis, with symptoms of transient ischaemic attacks, recovered cerebrovascular accident or amaurosis fugax in the appropriate territory. None of the surgeons treated asymptomatic stenosis. Only one (B2) had an upper age limit of 80 years.

The preoperative investigations at all the hospitals consisted of angiography, duplex scan and computed tomography. Postoperatively the patients at Hospitals A and B went to HDU. At Hospital E the patients were transferred to ITU and at Hospital D they returned to the vascular ward. The planned length of stay was 4–5 days for all of the hospitals where the procedure was performed.

The postoperative follow-up period ranged from 6 weeks to 5 years.

The only hospital where there was an endovascular treatment option for carotid stenosis was Hospital A, where it was being undertaken as part of a trial protocol.

Intermittent claudication

Treatment at all of the hospitals was on the basis of the claudication interfering with a patient's lifestyle and quality of life (QoL) rather than on a specific walking distance.

The tests performed in the majority of hospitals were ankle/brachial pressure index, angiography, stress test and Doppler studies. Surgeons at Hospitals C and F reported that angiography was not carried out for this indication.

Surgeons varied in their criteria for offering angioplasty. Angioplasty was available at all the hospitals except for Hospital D, where patients were referred to a larger centre. Surgery was stated to be the preferred treatment option for claudicants at all hospitals except Hospital A where angioplasty was reported to be preferred.

All patients were advised to stop smoking and to take exercise but only at Hospital B were patients allocated an appointment for an advice clinic.

Acute limb ischaemia

Intra-arterial thrombolysis was used at Hospitals A, B, C and F. Patients were usually treated on the vascular ward or on HDU (where available). The surgeon at Hospital F stated that he would have preferred the patients to go to ITU but there was pressure on the available ITU beds. Thrombolysis was not used at Hospitals D and E as the surgeons reported that they had experienced poor results in the past.

Chronic critical ischaemia

Surgical revascularisation was offered at all of the centres for a salvageable limb when reconstruction was considered possible. However, outside

Hospital A only two surgeons offered femoro-distal bypass and the surgeons who did not offer the procedure did not refer patients elsewhere. The planned length of stay for elective bypass was between 7 and 10 days.

The length of stay after amputation was extremely variable and was dependent on social and health factors rather than policy.

The only hospital with a limb-fitting centre was Hospital A. The other hospitals referred patients to this centre.

Varicose veins

The majority of surgery is planned as day-case, except for re-do and bilateral varicose veins, which in most centres requires an overnight stay. However, in Hospital A unilateral re-do surgery was carried out as a day-case and surgeon B1 operated on bilateral varicose veins on a day-case basis.

The majority of hospitals discharged the patients postoperatively to the care of the general practitioner with no hospital follow-up, though five surgeons reviewed patients on one occasion.

Chapter 3
Workload

The following data analysis is based on the Trent Regional Database for the financial years, 1995–96 and 1996–97. In order to obtain realistic averages, the data have been amalgamated for the 2 years, though it is accepted that there have been some changes over this period. The database was analysed using Microsoft Access and Microsoft Excel.

The database contains the encoded data for finished consultant episodes (FCEs) during the period in question. The fields include districts of residence, provider unit, patient age on admission, postcode, four procedural codes and dates, diagnostic codes, methods of admission and discharge, length of stay, sex and speciality.

The data include all patients who were treated within the region with approximately 30,000 inpatient episodes related to vascular services. Patients resident in the region but treated elsewhere are not included in the analysis; however, there are not thought to be major cross-boundary flows from the districts in question to districts outside the region.

For the purposes of calculating rates of particular procedures, the populations of districts based on OPCS projections for mid-1996 have been used.[11] Although the patient data have been anonymised, some linkage of records using a concatenation of postcode and date of birth has been carried out where necessary to look at issues regarding multiple admissions.

The need for casemix groupings

For the purposes of analysis, it is necessary to divide inpatient episodes into casemix groups. Such groups will be used to assess and compare workload and working practices, predict the effects of reconfiguration of services and to assess some of the issues surrounding resource use and outcome. Although no grouping will be ideal, there are certain criteria that the definitions of casemix groups should meet, as far as possible.

- The groups should be identifiable from the data that are currently available and routinely collected. The fields include procedural and diagnostic codes, speciality, method of admission, method of discharge, etc.
- The groups should be broadly coherent in resource terms for the purpose of assessing the resource implications of changes in practice as regards centralisation of services.
- The groupings should not be sensitive to the known common errors in coding.
- Each group should be expected to contain a sufficient number of episodes so that it is not subject to significant distortion due to exceptional cases.
- The groupings should be clinically related to allow realistic comparisons of clinical outcomes as performance indicators and to predict the effect of reconfiguration on expected outcomes.

Coding systems

The data that are routinely collected contain primary and subsidiary diagnostic codes using the International Classification of Diseases, tenth revision (ICD10)[20] and primary and subsidiary procedural codes using OPCS coding.[21] These can be used to generate Healthcare Resource Group (HRG) codes based on the third revision.[22]

All of the available systems have drawbacks in their application for the definition of casemix categories that are clinically relevant in terms of workload and expected outcomes. In the future it is to be expected that routine collection of more detailed information, such as Read coding[23] and risk data such as POSSUM scores,[24] may allow better comparisons of casemix.

Diagnostic codes

Diagnostic coding using ICD10 gives very little useful information regarding PVD. The majority of patients with arterial problems fall into the category “I702 – atherosclerosis of arteries of the extremities” or “I739 – peripheral vascular disease, unspecified”. This classification gives no useful distinction between clinically important subgroups, such as patients with critical ischaemia, gangrene or intermittent claudication. Such differences have very important implications for resource use and outcomes.

Although other, more specific codes are available (e.g. R02X – gangrene, not elsewhere specified, L97X – ulcer of lower limb, not elsewhere classified), they are not used consistently. For example, in the data reviewed the most common primary diagnosis for the patients undergoing major amputation are: I702 – atherosclerosis of arteries of the extremities; and I739 – PVD, unspecified. These two diagnoses accounted for 28.9% of the total number of cases.

Procedural codes

Similar problems exist with the use of procedural codes. In several areas there are codes that may overlap and lead to miscoding. For example, in the case of aortic surgery, there are separate categories for emergency aortic aneurysm repair (e.g. L184), elective aneurysm repair (e.g. L194) and emergency and elective bypass of the aorta (e.g. L204 and L214). In addition to this there are several non-specific codes that are frequently used. For example, of patients who were admitted electively with a diagnosis of AAA, over 25% have a procedural code that is non-specific, unspecified or should apply to emergency procedures.

Another example of lack of specificity that may be relevant is in the definition of varicose veins. Despite the fact that recurrent varicose veins represent between 10% and 20% of procedures, the specific code for recurrent varicose veins is very rarely used.

HRG version 3

HRGs were designed to produce resource-related clinical grouping of consultant episodes based upon procedural and diagnostic categories. The vascular groupings were extensively altered in the third revision,[22] with an increased number of groups being introduced.

The HRG groupings are based upon OPCS and ICD10 coding and suffer from many of the drawbacks noted above. For example, the failure of precise coding of emergency aortic surgery makes it likely that many emergency procedures are included in the ‘elective abdominal vascular surgery’ group (Q01) and vice versa. This may make little difference in terms of the overall effect on costs, though the recently published reference costs[25] suggest that the distinction between emergency and elective admission is more significant than the split between HRG groups (*Table 6*). However, due to the very substantial difference in outcomes that would be expected this may weaken the use of such groups in comparing performance. This may raise questions about the accuracy of estimates of mortality based on HRG groups.

TABLE 6 *Reference costs for aortic surgery (based upon HRG classification) versus mode of admission*

	Mode of admission	
HRG coding	**Emergency**	**Elective**
Q01 – Emergency aortic surgery	£4372	£3400
Q02 – Elective abdominal vascular surgery	£4209	£3976

This problem is illustrated in the recent publication of HRG data.[26] This reports a mortality of 10.92% following procedures in HRG Q02 but the high incidence of emergency admissions among this supposedly elective group (16.27%) suggests that the figures may be contaminated by the poorer expected results of emergency procedures.

Suggested casemix groupings

The definition of the following groups have been made on the basis of the available data, particularly the procedural codes and primary diagnosis. A full list of these definitions is given in appendix 1. It is not always the case that the most important procedure in terms of resource use or outcome is assigned to the primary procedure in the data returns. The general policy has been to define a hierarchy of vascular procedures and to look for the appropriate codes in any procedure field so that the episode is allocated to the group that is highest in the hierarchy. This hierarchy is given in appendix 1.

Aortic surgery

The HRG system defines two codes for aortic surgery: Q01 – emergency aortic surgery; and Q02 – elective abdominal vascular surgery.

Although it would make clinical sense to identify emergency and elective aneurysm surgery and aortic surgery for occlusive disease, as separate entities, it is clear that the difficulties in the OPCS coding described above give rise to inconsistencies and make the definition of these groups inaccurate. For example, *Table 7* shows the proportion of patients’ emergency and elective admissions with a diagnosis of AAA whose procedure is designated as emergency or elective on the basis of OPCS coding. It is possible that some of these are correctly coded, in that patients may be admitted as an emergency and then undergo elective procedures or vice versa.

***TABLE 7** Relationship between emergency and elective admission and procedural codes for patients undergoing aortic procedures*

	Elective admission	Emergency admission
Emergency procedure	3%	41%
Elective procedure	44%	12%

However, a review of the operating theatre system at the NGH shows that about 10% of patients whose operation is designated as emergency in the theatre system are miscoded as elective procedures in the OPCS system. This would result in them wrongly being assigned to HRG Q02 rather than Q01.

In order to attempt to get comparable data, the approach adopted has been to define emergency and elective aortic surgery groups on the basis of combining all infra-renal aortic surgical codes and those patients with a diagnosis of AAA admitted under a general surgical speciality code and divide them into emergency and elective admissions. The effect of this definition is that the groups do not correspond strictly to emergency aortic surgery as it is usually defined. However it does produce definitions that should be useful and comparable between the different districts and are not subject to the more common coding inconsistencies.

In addition to the operated cases, patients in whom the primary diagnosis is AAA, with or without mention of rupture, have been included and analysed as a subgroup. Analysis of the available data (*Figure 2*) show that there is a very wide variation in practice and that there may be a significant number of patients with ruptured aneurysm who are not offered surgery or who undergo a procedure that would not produce a vascular grouping under the HRG definitions.

The data show that in 26% of patients classified as emergency aortic cases on the current definition, the procedures would not produce a vascular grouping under the HRG definitions, and these patients had a mortality of over 80%. The procedures reported were consistent with the diagnosis. They included:

- T309 – unspecified opening of abdomen
- L912 – insertion/central venous catheter not elsewhere classified (vein-related ops.)
- M479 – unspecified urethral catheterisation of bladder
- X501 – direct current cardioversion (external resuscitation)
- X502 – external cardioversion not elsewhere classified (resuscitation).

When looking at the effects of alteration in policy for the management of emergency vascular admissions, the exclusion of such patients may result in a significant distortion of the outcomes

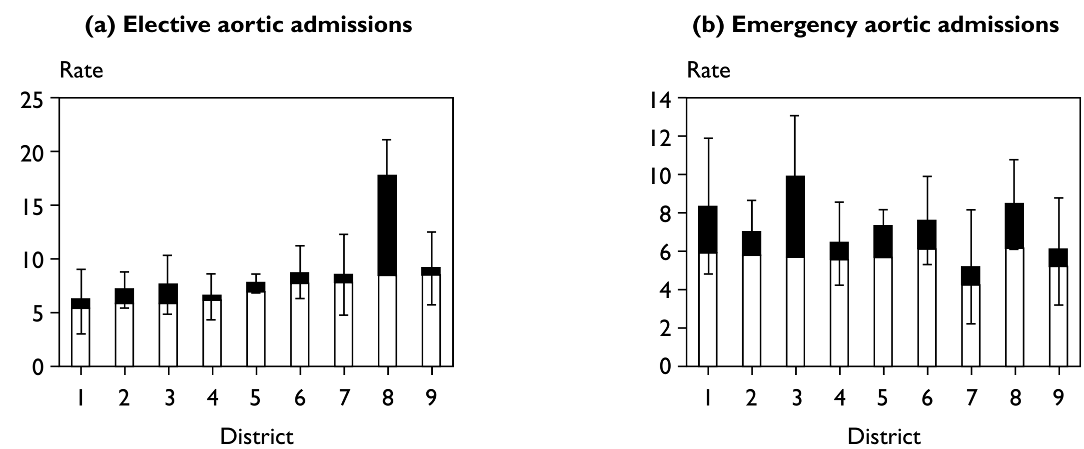

***FIGURE 2** Rates of aortic admissions (per 100,000 population per year) and procedures for all districts within Trent for (a) elective and (b) emergency admissions. Districts are in ascending order of total rates of elective aortic surgery. Error bars represent 95% CIs of total (■, unoperated; □, operated)*

and an inability to predict the effects of reconfiguration of services.

The inclusion of both aortic surgery for occlusive and aneurysmal disease is probably not a major problem, as aortic surgery for occlusive disease is becoming relatively uncommon. In the most recent year only 8% of aortic procedures were classified under the OPCS codes for bypass rather than replacement of aneurysmal aorta, and of these, 47% had a primary diagnosis of aortic aneurysm and were, thus, likely to have been bypasses for aneurysm rather than occlusive disease.

The HRG definitions of Q01 and Q02 include suprarenal aortic surgery and surgery to the visceral and renal vessels. These are uncommon and highly specialised procedures and already tend to be carried out in specialist centres. Although the small volumes mean that they are unlikely to significantly affect the estimates of resource use, the fact that they have high expected mortality means that they may distort the consideration of outcomes. For example, if a tertiary centre were to specialise in thoraco-abdominal aneurysm repairs and, as a result, 5% of their elective aortic cases had a 60% mortality, this might result in a doubling of overall mortality rates for this group. For these reasons, and because this group of patients are already treated by specialist centres, they have been identified as a separate casemix group.

The result of these considerations is that aortic vascular surgery has been divided into three categories as detailed in appendix 1.

- Supra-renal aortic surgery and surgery to the visceral vessels.
- Intra-abdominal vascular surgery/ emergency admissions.
- Intra-abdominal vascular surgery/ elective admissions.

PVD

The majority of vascular workload relates to PVD. Unfortunately, the current coding systems have some major drawbacks in considering diagnoses and procedures. The main problem is that the same procedures may be carried out for acute ischaemia, critical ischaemia and intermittent claudication and these cannot be separately identified from the coding system.

In order to define casemix categories for PVD, patients with relevant procedures in any field were included in the overall definition. Having identified the relevant episodes, patients with appropriate codes in any procedural fields were divided into categories for major amputation, femoro-distal reconstruction, other vascular reconstruction, minor amputation, angioplasty and angiography. The groups were identified in the given order of precedence so, for example, a patient recorded as undergoing major amputation and angioplasty in the same admission would be allocated to the former group, irrespective of the ordering of the recorded procedural codes. The relevant definitions are given in appendix 1. All these categories were subdivided into emergency and elective admissions.

Amputation

For the purposes of this study amputations have been divided into major amputations of the lower limb, which are those below, through or above the knee and minor amputations to include forefoot and toe amputations and operations on amputation stumps. The exact definitions are given in appendix 1.

Several problems arise in adequately defining major amputations. The first problem is that patients who undergo major amputations frequently have previous bypass grafts or minor amputations and the OPCS code may not appear in the field for the primary procedure. This is important as the resource implications of major amputation are considerably greater than most other categories. In the current data 13% of cases had an OPCS code for a major amputation in a second or subsequent position.

A second problem is that patients may undergo multiple amputations on the same limb, particularly if there are attempts to preserve length on the limb through more distal amputations. Although there is a code for "re-amputation at a higher level" (X121), this is not used consistently and the conversion of a below-knee amputation to above the knee may not be coded differently from a primary above-knee amputation. To address this issue requires careful analysis of linked data.

Another problem is that many amputations are not attributable to vascular services but are patients under the care of plastic surgeons or trauma and orthopaedic surgery. This can be addressed by limiting the casemix group on the basis of speciality to exclude these cases. In the current data, there is a significant proportion of such cases that are coded as medical and renal specialities (10.6%). This is presumably because it is not uncommon for a patient under the care of a renal or diabetic physician, to undergo amputation without the transfer of care to a surgeon. It is, therefore important to include these specialities in defining the casemix group. One note of caution in this respect is that, although it is not the practice in the districts studied, there are some areas in which amputations for vascular disease are carried out by orthopaedic surgeons[27] and this may present difficulties in ensuring comparable data.

The HRG for amputations (HRG Q15) includes arm amputations and hindquarter amputations. These have been excluded, as they are very different in terms of resource implications and are rarely carried out by vascular services. In the current data this probably makes little difference as, in the entire Trent region, there was not a single hindquarter amputation and only two upper limb amputations that were not carried out by orthopaedic or plastic surgeons.

Femoro-distal reconstruction

This subgroup corresponds to HRG Q04 (bypasses to tibial arteries).

Other vascular reconstruction

This category includes the remaining vascular surgical procedures to the vessels to the lower limbs. Attempts were made to subdivide this group to look at some of the issues relating to the site and type of reconstruction (e.g. vein versus prosthetic grafts). There is some difficulty in adequately defining such subgroups as patients may be coded as having non-specific vascular procedures that do not adequately define the sites of anastomosis or type of bypass.

Angioplasty

Endovascular treatment is not well coded within the OPCS system, as there are no codes for new procedures such as insertion of intra-arterial stents. There are also considerable doubts about the extent to which radiological procedures are consistently coded on information systems. For the purposes of this analysis this category corresponds to HRG Q12 (therapeutic endovascular procedures), except that carotid procedures are excluded for the reasons given below.

Angiography

This is defined based on the procedural code, however, there are likely to be considerable inaccuracies in this coding as experience shows that angiography is not routinely or accurately coded on discharge summaries. The data give little indication of total numbers of radiological procedures as they are not consistently recorded if they are a secondary procedure in an admission that includes other surgical procedures.

Carotid surgery

Carotid surgery has been defined on the basis of procedural codes, L291 to L309 inclusive, in addition to L311 and L318/9, the latter being the codes for angioplasty and transluminal procedures. These procedures are uncommon and are not included in the data for the majority of centres. However, some of the patients in Sheffield over the period of data collection have been entered into a multicentre randomised controlled trial (RCT), in which patients have been randomised to receive either CE or angioplasty.[28] As all of these patients had the indications for carotid surgery and without this trial would normally undergo carotid surgery, these cases have been included for the purpose of calculation of rates.

Upper limb surgery

Carotid surgery is defined in the HRG documentation as: Q05 – extra-cranial or upper limb surgery. From the point of view of the organisation of vascular services upper limb surgery presents different issues to carotid surgery and has, therefore, been identified as a separate category.

Varicose veins

Both general and vascular surgeons carry out varicose vein operations. The description of the group corresponds to HRG Q11.

Summary of casemix groups

These are the casemix groups that have been defined, taking into account the above considerations. Where appropriate these are divided into subgroups depending upon whether the admission was emergency or elective.

- Supra-renal aortic surgery and surgery to the visceral vessels.
- Intra-abdominal vascular surgery/ emergency admissions.
- Intra-abdominal vascular surgery/elective admissions.
- Carotid surgery.
- Upper limb surgery.
- Varicose veins.

PVD is divided into the following six categories, each of which is sub-divided into emergency and elective categories.

- Major amputation.
- Femoro-distal reconstruction.
- Other vascular reconstruction.
- Minor amputation.
- Angioplasty/endovascular.
- Angiography.

Workload analysis

The data set has been analysed in order to identify important workload issues for each of the casemix groups described above. Particular issues have been addressed, some being more relevant than others to specific casemix groups.

The following specific issues have been addressed for each of the casemix groups.

- The rates of admission to hospital by the district of residence.
- The number of cases treated by each provider unit.
- Any information that is available about casemix, diagnostic groups or demographics.
- Current cross-boundary flows.
- Re-admissions to the same or other hospitals during this study period.
- Information regarding secondary procedures within a single admission.

Each of these issues has been considered specifically for the districts within North Trent and, where available, this has been compared with wider data for Trent and the rest of the UK.

Admission rates

The admission rates for the three casemix groups relating to aortic surgery or aneurysm are given in *Table 8* along with the 95% confidence intervals (CIs). As can be seen the rate of admission in the supra-renal aortic surgery group is very low, with wide CIs due to the very small number of cases carried out in each centre. For the other aortic groups there is quite marked variation in overall rates. Some of this may be explained by patients being admitted on separate occasions for investigations and procedures.

Figure 2 shows the overall rates of aortic admissions for all patients in Trent with separate identification of those in which there was no operative procedure. As can be seen there is very wide variation in the proportion undergoing surgery for both emergency and elective admissions. Graphical examination of the data do not suggest an inverse relationship between emergency and elective admission. The implication of this is that the variability in emergency rates is unlikely to be a result of more, or less, aggressive treatment of asymptomatic aneurysm in any particular district.

The rates of emergency admission for patients in the PVD categories are given in *Table 9* and for elective admissions in *Table 10*. As can be seen from these tables, approximately a third of patients admitted for vascular intervention for PVD are admitted as an emergency. The total rates of procedure are comparable between districts within the bounds of the CIs. However, within this, there is considerable variation in the sorts of procedures carried out, with a five-fold variation in the rates of angioplasty and femoro-distal bypass, and approximately 50% variation in major amputation rates.

Table 11 shows the rates of the remaining vascular casemix categories. As can be seen there is a three-fold variation in the rate of CE. The overall rates of upper limb surgery are low, and the rates of varicose vein surgery vary by approximately 50%.

Cross-boundary flows

There are small cross-boundary flows between all neighbouring districts, which are in the order of 1–2%. These occur in both directions and largely

***TABLE 8** Number of admissions (per 100,000 population per year) (95% CI) for abdominal aortic aneurysm or aortic surgery*

	Supra-renal AAA	Aortic – elective	Aortic – emergency
Barnsley	1.77 (0.54 to 2.99)	8.33 (5.67 to 10.99)	5.08 (3.00 to 7.16)
Doncaster	0.34 (–0.13 to 0.81)	8.97 (6.56 to 11.39)	5.89 (3.93 to 7.84)
North Derbyshire	1.19 (0.41 to 1.97)	9.76 (7.53 to 11.99)	6.80 (4.94 to 8.66)
North Nottinghamshire	1.02 (–0.35 to 2.39)	7.52 (3.81 to 11.23)	9.83 (5.59 to 14.07)
Rotherham	0.78 (0.02 to 1.54)	5.99 (3.87 to 8.11)	8.29 (5.80 to 10.78)
Sheffield	0.57 (0.11 to 1.02)	6.38 (4.85 to 7.90)	6.34 (4.82 to 7.86)
Total	**0.98 (0.66 to 1.31)**	**7.68 (6.78 to 8.59)**	**7.27 (6.38 to 8.15)**

TABLE 9 *Number of emergency admissions (per 100,000 population per year) (95% CI) for procedures related to PVD*

	Barnsley	Doncaster	North Derbyshire	North Nottinghamshire	Rotherham	Sheffield	Total
Major amputation	11.05 (7.99 to 14.11)	12.87 (9.97 to 15.76)	11.53 (9.11 to 13.96)	11.24 (6.70 to 15.77)	9.16 (6.54 to 11.78)	7.59 (5.92 to 9.25)	9.22 (8.22 to 10.21)
Femoro-distal	0.44 (–0.17 to 1.05)	0.34 (–0.13 to 0.81)	0.40 (–0.05 to 0.85)	0.51 (–0.46 to 1.48)	0.39 (–0.15 to 0.93)	1.52 (0.77 to 2.26)	0.99 (0.67 to 1.32)
Reconstruction	7.95 (5.36 to 10.55)	8.13 (5.83 to 10.43)	8.62 (6.52 to 10.71)	5.49 (2.32 to 8.66)	6.63 (4.40 to 8.85)	12.52 (10.38 to 14.65)	8.10 (7.17 to 9.04)
Minor amputation	1.55 (0.40 to 2.69)	5.42 (3.54 to 7.29)	1.46 (0.60 to 2.32)	4.85 (1.87 to 7.83)	3.12 (1.59 to 4.65)	5.50 (4.08 to 6.92)	3.36 (2.76 to 3.96)
Angioplasty	1.77 (0.54 to 2.99)	7.62 (5.39 to 9.84)	4.51 (2.99 to 6.02)	6.64 (3.15 to 10.12)	4.48 (2.65 to 6.31)	7.87 (6.18 to 9.56)	6.70 (5.85 to 7.55)
Angiography	5.30 (3.18 to 7.42)	8.97 (6.56 to 11.39)	7.69 (5.71 to 9.67)	6.00 (2.69 to 9.31)	9.55 (6.88 to 12.22)	12.61 (10.47 to 14.76)	7.30 (6.41 to 8.19)
Total vascular treatments	**22.76 (18.36 to 27.15)**	**34.37 (29.64 to 39.10)**	**26.51 (22.84 to 30.19)**	**28.73 (21.48 to 35.98)**	**23.78 (19.56 to 27.99)**	**34.99 (31.42 to 38.56)**	**28.37 (26.62 to 30.12)**

TABLE 10 *Number of elective admissions (per 100,000 population per year) (95% CI) for procedures related to PVD*

	Barnsley	Doncaster	North Derbyshire	North Nottinghamshire	Rotherham	Sheffield	Total
Major amputation	5.30 (3.18 to 7.42)	4.40 (2.71 to 6.09)	5.57 (3.88 to 7.25)	5.49 (2.32 to 8.66)	2.53 (1.16 to 3.91)	3.13 (2.06 to 4.20)	4.05 (3.39 to 4.71)
Femoro-distal	1.10 (0.14 to 2.07)	0.51 (–0.07 to 1.08)	0.40 (–0.05 to 0.85)	1.28 (–0.25 to 2.81)	0.00 (0.00 to 0.00)	1.33 (0.63 to 2.02)	1.27 (0.90 to 1.64)
Reconstruction	13.26 (9.90 to 16.61)	11.34 (8.63 to 14.06)	9.94 (7.69 to 12.19)	7.02 (3.44 to 10.61)	9.55 (6.88 to 12.22)	12.71 (10.56 to 14.86)	10.26 (9.21 to 11.31)
Minor amputation	1.55 (0.40 to 2.69)	3.22 (1.77 to 4.66)	1.72 (0.79 to 2.66)	3.70 (1.10 to 6.31)	3.31 (1.74 to 4.89)	3.41 (2.30 to 4.53)	2.67 (2.14 to 3.21)
Angioplasty	21.43 (17.17 to 25.70)	38.94 (33.91 to 43.97)	21.87 (18.54 to 25.21)	34.35 (26.42 to 42.27)	33.33 (28.33 to 38.32)	33.48 (29.98 to 36.97)	31.77 (29.93 to 33.62)
Angiography	50.82 (44.26 to 57.39)	47.41 (41.85 to 52.96)	38.58 (34.15 to 43.01)	25.15 (18.37 to 31.94)	63.34 (56.45 to 70.22)	65.81 (60.92 to 70.71)	39.82 (37.75 to 41.89)
Total vascular treatments	**42.65 (36.63 to 48.66)**	**58.41 (52.25 to 64.57)**	**39.51 (35.02 to 43.99)**	**51.84 (42.11 to 61.58)**	**48.72 (42.68 to 54.76)**	**54.05 (49.62 to 58.49)**	**50.03 (47.71 to 52.35)**

TABLE 11 *Number of other admissions (per 100,000 population per year) (95% CI) for vascular procedures*

	Barnsley	Doncaster	North Derbyshire	North Nottinghamshire	Rotherham	Sheffield	Total
Carotid	2.43 (0.99 to 3.87)	5.25 (3.40, 7.10)	4.37 (2.88 to 5.87)	4.72 (1.78 to 7.66)	4.48 (2.65 to 6.31)	7.59 (5.92 to 9.25)	5.95 (5.15 to 6.74)
Upper limb	3.31 (1.64 to 4.99)	0.68 (0.01 to 1.34)	1.99 (0.98 to 2.99)	2.04 (0.11 to 3.98)	1.56 (0.48 to 2.64)	1.23 (0.56 to 1.90)	1.45 (1.06 to 1.85)
Varicose veins	123.08 (112.86 to 133.29)	151.87 (141.94 to 161.80)	104.60 (97.30 to 111.89)	113.64 (99.23 to 128.05)	134.67 (124.63 to 144.70)	114.94 (108.47 to 121.40)	116.19 (112.66 to 119.72)

relate to areas on the boundaries between districts. The largest cross-boundary flows are between Sheffield and the surrounding districts. *Table 12* gives the percentage of patients for each district and casemix group that are treated in Sheffield. These percentages are based on all those treated within North Trent. The figures for North Nottinghamshire relate to the proportion of those patients treated either in Worksop or Sheffield, and exclude the remainder of North Nottinghamshire.

As can be seen, Sheffield deals with the majority of the vascular workload from Worksop with only the varicose veins and a proportion of the major and minor amputation being carried out in Worksop. The majority of carotid surgery for all North Trent districts is carried out in Sheffield, which also takes a significant proportion of the aortic and peripheral vascular work from surrounding districts.

For all districts the overall proportion of cases treated by Sheffield is higher for the emergency than for elective admissions.

Rates of procedures for provider units

The number of aortic procedures carried out in individual provider units per year over the 2-year period of the study is given in *Table 13*. This gives the number of primary aortic procedures rather than the number of admissions in each of these categories. Only Sheffield carries out more than ten emergency aortic procedures per year.

Table 14 shows the number of admissions for the PVD groups. It is notable that the districts other than Sheffield that carry out femoro-distal bypass do only 2–3 of these procedures per year.

TABLE 12 *Proportion of admissions to Sheffield for patients resident in catchment area*

	Barnsley	Doncaster	North Derbyshire	Worksop	Rotherham
Supra-renal AAA	17%	50%	40%	100%	100%
Aortic – elective	23%	14%	14%	100%	36%
Aortic – emergency	9%	1%	17%	100%	29%
Carotid	100%	89%	95%	100%	96%
Upper limb	15%	75%	18%	100%	63%
Major amputation – emergency	12%	10%	12%	52%	15%
Femoro-distal – emergency	50%	50%	0%	100%	100%
Reconstruction – emergency	36%	15%	19%	100%	41%
Minor amputation – emergency	14%	9%	14%	50%	31%
Angioplasty – emergency	38%	4%	24%	100%	26%
Angiography – emergency	25%	17%	26%	100%	27%
Major amputation – elective	22%	8%	19%	67%	38%
Femoro-distal – elective	33%	0%	0%	100%	100%
Reconstruction – elective	26%	3%	22%	100%	16%
Minor amputation – elective	29%	6%	9%	100%	24%
Angioplasty – elective	34%	7%	20%	100%	28%
Angiography – elective	32%	17%	31%	100%	20%
Varicose veins	12%	0%	11%	4%	8%

TABLE 13 *The number of aortic procedures carried out in individual provider units (average per year)*

	Barnsley	Doncaster	North Derbyshire	Worksop	Rotherham	Sheffield
Aortic – elective	11.5	18	25	0	8	58.5
Aortic – emergency	4.5	7.5	10	0	4.5	48

***TABLE 14** The number of vascular cases treated in individual provider units (average per year)*

	Barnsley	Doncaster	North Derbyshire	Worksop	Rotherham	Sheffield
Major amputation	31.5	46	55.5	7.5	24	92
Femoro-distal	2	2	3	0	0	19.5
Reconstruction	33.5	53	56	0	30.5	190
Minor amputation	5.5	23.5	10.5	2.5	12	62.5
Angioplasty	34.5	128.5	79	0	70	335.5
Angiography	87	138	122	0	148	606

***TABLE 15** The number of other procedures carried out in individual provider units (average per year)*

	Barnsley	Doncaster	North Derbyshire	Worksop	Rotherham	Sheffield
Carotid	0	1.5	1	0	0.5	91
Upper limb	6.5	0.5	6	0	1.5	15
Varicose veins	245	448.5	351	114.5	318	715

Table 15 gives the number of procedures in the other categories. Again, it is notable that those districts other then Sheffield carrying out carotid procedures do so very rarely.

Casemix and demographics

Some information is available on the casemix and demographics from information such as age, diagnostic data and different procedural codes within the casemix categories.

The group of supra-renal aortic surgery and visceral procedures is a rather heterogeneous group. The majority of cases in Sheffield were elective admissions for patients undergoing surgery for supra-renal aneurysm or visceral vessel disease, whereas the occasional cases in other centres were all emergency admissions of aortic aneurysms designated as supra-renal.

In the case of aortic patients there was considerable variability in the casemix as regards age. In the case of emergency aortic admissions 28% of the admissions were over the age of 80 years, but these patients were less likely to receive surgery than the average. There was considerable difference between the teaching hospital where 77% of those admissions who were over the age of 80 years underwent surgery, compared with figures of 16–25% in the other districts.

In the case of elective aortic surgery, those patients over 80 years accounted for an average of 6% of elective aortic procedures, but in two districts there were no elective aortic procedures on patients over the age of 80 years.

Within the PVD group there was variation between the rates of particular procedures as described above. Within these casemix categories there was also some variation in the sort of procedures that were being carried out. In the case of amputation, 44% of procedures were carried out at the below-knee level but 4% of these went on to have a second amputation at a higher level during the same admission. The proportion of amputations carried out at the below-knee level varied between 20% and 54%.

Within the vascular reconstruction group, the most common individual procedures were femoro-popliteal bypass followed by femoral embolectomy and femoro-femoral crossover. No other procedure was carried out on more than five occasions per year in any district other than Sheffield. Of the femoro-popliteal bypasses, 32.4% were carried out using prosthetic material with the rate ranging from 10% to 70%. Sheffield used prosthetic material less than half as often as the average for the other North Trent districts.

Secondary procedures

Procedures were classified based on the hierarchy given in appendix 1, so that patients undergoing more than one procedure during the same admissions would be classified under the main procedure. Secondary procedures within the same admission were identified by noting cases in which there was another procedural code with a different procedural date to the first and using this to identify a secondary casemix group. Many patients have more than one procedural code for a single procedure so that only procedures carried out on a different date were considered. The effect of this is that some secondary procedures carried out on the same day as the initial procedure may have been missed.

Table 16 shows the proportion of aortic cases in which a secondary procedure was carried out during the same admission. In the case of aortic procedures the inability to identify separate procedures on the same day may be significant, as local data at the NGH show that approximately 3% of patients undergo re-operative procedures on the same day as their initial procedure.

Table 17 shows the rate of secondary procedures for patients in each of the casemix categories. Again this table only relates to secondary procedures carried out on a separate occasion and, for example, patients undergoing a reconstruction with a minor amputation at the same time will not be included.

A substantial number of patients undergo secondary procedures during the same admission and as discussed previously it seems likely that the data, particularly for radiological procedures are incomplete making this an under-estimate of those procedures.

In the other casemix categories there were small numbers of secondary procedures. Approximately 1% of carotid cases underwent a secondary procedure. In the upper limb casemix category 16% of patients underwent angiography and a further 16% underwent a secondary upper limb procedure in the same admission.

Re-admissions

To identify multiple admissions and re-admissions a case identifier was constructed from a concatenation of the postcode and date of birth.

TABLE 16 *The proportion of aortic admissions in which a secondary procedure was recorded in the same admission*

	Supra-renal AAA	Aortic	Major amputation	Femoro-distal	Reconstruction	Minor amputation	Angioplasty	Angiography
Supra-renal AAA	11%	22%	0%	0%	0%	0%	0%	11%
Aortic – elective	0%	2%	0%	1%	1%	0%	1%	3%
Aortic – emergency	0%	1%	0%	0%	1%	0%	0%	5%

TABLE 17 *The proportion of admissions with PVD in which a secondary procedure was recorded in the same admission*

	Major amputation	Femoro-distal	Reconstruction	Minor amputation	Angioplasty	Angiography
Major amputation – emergency	13%	6%	27%	8%	19%	27%
Femoro-distal – emergency	–	38%	43%	4%	17%	77%
Reconstruction – emergency	–	–	14%	4%	20%	55%
Minor amputation – emergency	–	–	–	6%	6%	9%
Angioplasty – emergency	–	–	–	–	6%	12%
Angiography – emergency	–	–	–	–	–	54%
Major amputation – elective	4%	13%	12%	2%	13%	17%
Femoro-distal – elective	–	–	29%	0%	0%	49%
Reconstruction – elective	–	–	9%	1%	8%	17%
Minor amputation – elective	–	–	–	2%	6%	4%
Angioplasty – elective	–	–	–	–	5%	7%
Angiography – elective	–	–	–	–	–	17%

In this way re-admissions to the same or other providers could be identified. In the case of aortic surgery there were very few patients identified as being admitted to more than one provider unit. There are a significant number of emergency transfers of aortic aneurysm to Sheffield from the surrounding districts. However, the majority of these are transferred directly from the accident and emergency department and are not, therefore, registered as admissions at the initial hospital.

In the case of elective admissions for aortic aneurysm there are a significant number of patients who undergo separate admissions for investigation and assessment. It can be seen from *Figure 2* that practice is very variable with some districts appearing to admit almost every elective aortic case on at least one other occasion.

In the case of PVD, patients frequently had more than one admission over the 2-year period with an average of 1.33 admissions per patient. These figures varied from 1.25 to 1.51 for the different districts of the study.

In the case of major amputation, 7% of patients went on to to be re-admitted for a second major amputation during the 2-year period. The coding for the side of procedure is not used consistently. It is therefore impossible to tell to what extent there were re-amputations of the same limb or whether they were of the other leg.

Discussion

There are a number of papers from both within the UK and from elsewhere that provide some estimates of vascular workload.[29,30] In comparing these it must be remembered that there are differences in the classification of patients in the different studies that may lead to some discrepancies. However, it can be seen from *Table 18* that the estimates are broadly comparable.

There are a number of points that arise from this workload analysis that give rise to concerns or may have significant implications for the configuration of vascular services.

There is considerable variation in the rates of certain procedures. This was particularly noted in those areas that are complex or relatively recent innovations, such as CE, femoro-distal bypass, and angioplasty. All of these are offered at a higher rate in the teaching district than in the surrounding districts. It is notable that where these services are not offered locally there is a tendency for patients not to be referred to the specialist centre for such treatments. There would also appear to be considerable variation in the rate of major amputation and this appears to be inversely related to the rates of vascular reconstruction (see chapter 5, *Rates of reconstruction and amputation*).

Certain complex vascular procedures appear to be carried out very infrequently in some districts and this must raise concerns about the maintenance of the necessary skills among staff. This is particularly true of emergency and elective aortic surgery, CE and femoro-distal bypass.

There would appear to be some variability in the selection of patients and choice of procedures, which gives rise to concern. Particular aspects in which this is the case include the following.

- The proportion of patients admitted with aortic aneurysm who undergo surgery varies considerably from district to district demonstrating

TABLE 18 *Published rates of admission (per 100,000 population per year) for vascular cases[29] and current study results**

Source	East Dorset	Northern Ireland 1994	Northern Ireland 1996–97	Scotland 1995	Denmark 1996	Sweden 1995–96	Finland 1995	Trent 1994–95	North Trent 1995–97*
Aortic aneurysm/surgery	19	15	13	18	16	11	10	9.3	**14.9**
CE	6	8	9	7	4	6	12	3.8	**5.9**
PVD	36	42	37		35	41	43		**78.4**
Femoral reconstruction								9.2	
Major amputation								12.3	**13.3**
Varicose veins	130	87		160					**116.0**

differences in policy regarding admission, which may distort estimates of workload based purely upon FCEs.

- The proportion of patients admitted as an emergency with aortic aneurysm, who undergo surgery is very variable.
- Some providers do not appear to undertake elective aortic surgery on patients over the age of 80 years, and there is variability in the proportion of such patients admitted as an emergency who undergo surgery.
- There is variation in the proportion of patients in whom prosthetic material is used for femoro-popliteal bypass.
- There is variation in the proportion of major amputations that are carried out at the below-knee level.

One other issue that arises from an analysis of workload is the difficulty that exists in identifying some important features from the coded information. In particular, new procedures are not coded, so that important developments, such as arterial stenting and intra-arterial thrombolysis are not separately identifiable from the data. There is separate evidence from interviews with consultants in different districts that there may be considerable variability in the rate at which these procedures are offered.

Chapter 4
Outcomes

Introduction

Several specific areas have been noted in the interviews and workload analysis in which there would appear to be differences in practice and workload that may have implications for outcomes. In this section the effects of each of these aspects of the services will be considered separately with regard to the likely influence that any reconfiguration of services might have upon outcomes. This evaluation has taken place partly through the consideration of local data, where this is appropriate, and partly through a review of the literature.

Due to limitation in the availability of resources it has not been possible to carry out full systematic reviews in all necessary areas and, as detailed below, certain areas have been given priority in this respect.

One of the key issues that arose from the workload analysis is the concern regarding complex major vascular procedures that are carried out at very low volumes in some districts. This is clearly a major issue in respect of the organisation of services in that it reflects the degree of centralisation and specialisation that has occurred. This issue has been approached by carrying out a full systematic review of the relationship between volume and outcome in respect of vascular surgical procedures. This has been supplemented by a consideration of evidence that is available locally regarding the outcome of specific procedures.

Another important issue, which may influence the arrangement for the provision of services, is the need for emergency radiological services. An important example of this is intra-arterial thrombolysis, which is only offered at a limited number of centres. There are doubts about the efficacy of this procedure and a systematic review has therefore been carried out to identify and evaluate the magnitude of any benefit of this procedure in the reported literature. This is necessary in order to determine the extent to which it should be allowed to influence the organisation of services.

Another issue is the availability of CE. There have been some large international multicentre RCTs, which have provided high-quality data about the likely benefits of this procedure. These have been reviewed, but, due to resource limitations, a full systematic review has not been carried out.

The issue of the relationship between vascular reconstruction and the rate of major amputation is a concern and has been raised by the analysis of workload. This is not an area that would be amenable to RCTs but there are a number of published observational studies, which have been reviewed. A full systematic review would be desirable but was not possible within the resources available.

The issue of differences in the use of graft materials for vascular reconstruction was highlighted in the workload analysis. This is a possible source of difference and a potential source of variation in outcome. It is, however, currently the subject of a systematic review by the PVD group of the Cochrane Collaboration.[31] A further systematic review has not therefore been carried out, but the results of the Cochrane review have been summarised.

The availability and use of angioplasty for PVD has also been highlighted as a potential cause of differences in outcome. There is a lack of suitable RCTs in this area. This is partly due to the difficulty that exists in designing such trials, as the treatments are not strictly alternatives in that angioplasty does not preclude the use of surgery. There is also known to be considerable variation in the results of angioplasty in different anatomical situations. This matter was examined in more detail using methods of decision analysis, as described in the next chapter.

Use of routine data

It would clearly be an advantage if it was possible to judge the quality of outcome from data that are routinely collected and this is the basis of recent publications by the NHS Executive suggesting possible performance indicators.[32] At present, none of the suggested indicators relate to the workload of vascular services. The data relating to the Trent region have been analysed in order to try to establish whether any of the available information may be used as indicators of outcome. There are a number of fields that may potentially be useful in this respect and these are considered below.

Mortality

Although it is not possible to get strict indications of 30-day or long-term mortality without linkage to death certification, the hospital data do contain discharge information, which identifies cases in which the inpatient episode ends in death. This may, therefore, give some measure of inpatient mortality following particular procedures.

There are a number of potential drawbacks with the use of mortality data recorded in this way.

- In most of the casemix groups the expected mortality is so low that the sample size for any individual provider would not be sufficient for mortality to be a useful indicator of outcome.
- There is a potential problem with patients who are excluded from data because they are transferred to another hospital prior to death so that the mortality is not recorded.
- The usefulness of mortality as a performance indicator may be limited by difficulties in the extent to which comparisons are appropriate due to differences in casemix, and by a lack of sufficient supplementary information to correct for important aspects of this.

Amputation

Much of the work of reconstructive vascular surgery is for the purpose of limb salvage in patients with critical ischaemia.[33] Limb salvage rate is often considered a reasonable estimate of success and thus the number of amputations carried out may be a useful indicator of outcome. In addition to this, the level at which major amputation is carried out is known to relate to the extent of rehabilitation[34] and is thus related to QoL following surgery.

Length of stay

It may be possible to use length of stay as an indicator of quality, in that patients who suffer complications of treatment are more likely to require an extended stay in hospital. There are several other factors that may influence length of stay, including inefficiencies in the provision of service, social factors and availability of convalescence so that this is unlikely to be a satisfactory measure on its own.

Re-admissions/re-operations

Re-admission of patients to hospital within a defined period following discharge may be an indication of the occurrence of complications.

Multiple procedures during the same admission may also be a proxy measure of poor outcome, in that second and subsequent procedures may relate to complications. There is however some doubt about the accuracy with which subsidiary procedures are recorded which may limit the usefulness of this measure (see chapter 3, *Secondary procedures*).

The relationship between volume and outcome

Local data

In the workload analysis it is clear that there are a number of conditions in which the overall number of procedures carried out in some centres is low. This raises the issue of the possible relationship between the volume of procedures and the outcome of treatment. If this effect does occur it is likely to be most apparent for procedures that are particularly complex and have a high risk of serious adverse outcomes. Aortic and carotid surgery fall into this category, but in the latter the service is largely centralised already, and the number of cases carried out in the smaller districts is too low to obtain meaningful estimates of outcome.

Both elective and emergency aortic surgery are known to have significant mortality and this is probably the most useful outcome indicator that is available in these conditions. In the current analysis the casemix groups do not correspond exactly to reported HRGs or other publications for the reasons given above, though in numerical terms the differences are fairly small.

In respect of elective aortic surgery the published data for HRG Q02 reports a figure of 10.92% as overall mortality.[26] This is considerably higher than other published data. The recent Small Aneurysm Trial reported a mortality of 7.1% in surgical procedures on the group that were randomised to conservative measures,[19] and this probably represents a realistic estimate of the mortality within the hospitals participating in the trial. The mortality in the group randomised to early surgery was lower (5.8%), but may represent a comparatively low-risk group. Large studies published from single centres have tended to report rather lower mortality.[35]

TABLE 19 *In-hospital mortality (95% CI) following aortic surgery in Sheffield and surrounding districts*

	Sheffield	Surrounding districts
Elective	4.2% (0.9% to 7.4%)	10.5% (5.5% to 15.5%)
Emergency	30.4% (22.3% to 38.5%)	59.4% (49.8% to 69.0%)
Emergency (including unoperated cases)	35.1% (27.0% to 43.2%)	75.4% (68.9% to 82.0%)

In the current data the recorded mortality for the group of elective cases undergoing aortic surgery varies between 5% and 22%. *Table 19* gives the mortality (and 95% CIs) for aortic surgery carried out in Sheffield and combined figures for the other North Trent provider units. A similar calculation for the group undergoing aortic surgery following emergency admission shows that mortality ranges between 30% and 76% with similar differences between Sheffield and the other Trent providers.

The figures for mortality following emergency surgery do not include those patients who do not undergo a vascular procedure. The table also shows the mortality including those patients with a primary diagnosis of aortic aneurysm who died after being admitted as an emergency with a surgical speciality code. It can be seen that overall mortality varies between 35% and 85%.

One possible confounding factor is the selection of casemix in those patients transferred between different centres. *Table 20* shows the mortality for patients treated in Sheffield broken down into those patients who are resident in the Sheffield district and those who were admitted from outside the district. This demonstrates that elective admissions from outside Sheffield had a higher operative mortality than those from within Sheffield, whereas the converse was true of those patients admitted as an emergency. This is in keeping with selection taking place, in that the elective referral to Sheffield would be more likely in complex or difficult cases, whereas the transfer process for emergencies may select the lower-risk patients.

TABLE 20 *In-hospital mortality following aortic surgery in Sheffield for local patients and tertiary referrals from surrounding districts*

	Local	Tertiary
Elective	3.4%	5.3%
Emergency	33.8%	25.0%
Emergency (including unoperated)	40.7%	25.0%

In view of the great importance of the relationship between volume and outcome in configuring services a systematic literature review has been carried out to consider this issue in greater detail.

Published data

There is a commonly held view that better healthcare outcomes are associated with hospitals and/or clinicians that carry out large volumes of activity. The belief that there is a positive volume–outcome relationship is well supported, as evidenced by the large number of volume–outcome studies reported in the literature.[36] However, doubts have recently been expressed as to the validity of the results of such studies.[37,38]

The existence (or otherwise) of a positive volume–outcome relationship is a potentially important factor in how services are structured. For example, for a small sub-speciality, such as vascular surgery, to benefit from a positive volume–outcome relationship may require considerable restructuring of the service to ensure patients have access to a suitable specialist with adequate experience in all the relevant procedures. Such restructuring may have considerable costs associated with it, and may have other disadvantages, such as denying patients local access to services and increasing travelling times. It is therefore crucial that before any restructuring is undertaken, the supposed benefits of any change should be established.

The evidence for the existence, or otherwise, of a positive volume–outcome relationship in the area of peripheral vascular surgery has been examined. To do this, a systematic review of the journal literature between 1986 and 1998 inclusive was undertaken in order to identify all relevant volume–outcome studies in the area. The methodology of the systematic review and the criteria used to select articles are described in the next section. The review identified 36 volume–outcome studies, which were categorised into three distinct areas – CE, AAA repair and other vascular interventions. For each area, a distinction is made between those studies that made adjustments for casemix differences and those that did not. The main findings of each study are discussed and a summary is presented of the collective evidence.

Search strategy

The key focus of the literature search was to identify articles dealing with issues specifically concerning volume–outcome relationships in the area of peripheral vascular surgery. The first stage of the search was to consult the Cochrane Library, the result of which was the identification of the Trials Register of the Peripheral Vascular Disorders Review Group of the Cochrane Collaboration. It was decided that in order to optimise the resources for the review, high-quality sources of evidence, already identified by the Review Group, would be used. This prevented a duplication of efforts and allowed concentration on areas not covered by the Cochrane Group.

The next stage was to construct a search strategy to use with the electronic databases. The NHS Centre for Reviews and Dissemination (CRD) has recently been involved with a major review of the relationship between volume and outcome.[39] A copy of the search strategy used by the CRD Review team was acquired and served as a useful starting point for the development of a more sensitive strategy for this particular review.

The main databases used were MEDLINE, EMBASE (*Excerpta Medica*), Science Citation Index (all via the BIDS service), HealthSTAR, DHSS-DATA, HELMIS (Nuffield Institute for Health, University of Leeds) and the Cochrane Library. Relevant citations from retrieved articles were identified once these articles had been obtained and scrutinised. In this way the corpus of the literature was extended to compensate for any materials that might have been missed due to the inadequacies of the indexing languages. For similar reasons the search strategy used was a very sensitive one, that is one that erred on the side of retrieval of more items than were required in order to ensure that these bibliographic records were assessed. Details of the keywords used in the search are listed in appendix 2.

Due to tremendous heterogeneity of search terms for volume–outcome studies a final check was applied to this search. First, a citation search was carried out for a number of seminal articles on the relationship between volume and outcome in vascular surgery, which revealed quite a consistent body of literature associated with the topic. Second, a general search for volume and outcome studies in surgery was conducted in order to establish both a theoretical base, and to ensure that no relevant studies had been missed through inadequate indexing.

A number of exclusion criteria were applied to the selection of articles. An article was rejected if it conformed with one or more of the following criteria.

- It was not written in English.
- It was not published in a peer-reviewed journal.
- It was an editorial, letter or an abstract.
- The article did not address the issue of volume and outcome within its content.
- Volume is addressed but not clearly defined, i.e. if all that is referred to is 'high' and/or 'low' volume.

The abstracts of the articles that had been identified by the search were read, and any articles that could definitely be rejected on the basis of the above criteria were rejected. This left 60 articles, which were obtained and subjected to further scrutiny. The articles were independently read and then discussed by two of the authors. Any articles for which there were any doubts/disagreements were passed on to a third person for their opinion. This process resulted in 24 articles being rejected, thus leaving 36 papers to be included in the review.[40–75]

The importance of adjusting for casemix

Before presenting the results of the review, it is necessary to highlight the effect that differences in casemix can have on the results of volume–outcome studies. There is a tendency in volume–outcome studies for the results to be reported for the whole sample of patients. It is important to be aware that results reported in this way may be misleading as no account is taken of the diversity of patient characteristics, which these samples may contain. For example, differences in factors such as severity of illness or risk of adverse outcomes among patients can significantly affect any relationship between volume and outcome. This is illustrated by Sowden and Sheldon,[38] who discuss examples from coronary artery bypass grafting and intensive care to demonstrate the importance of adjusting for casemix. With respect to coronary artery bypass grafting, they report that the strength of the relationship between low volume and increased mortality is reduced in studies that adjust for differences in risk among patients receiving treatment. With adult intensive care, they cite a study by Jones and Rowan,[37] in which the apparent higher mortality associated with smaller ITUs ceased to be significant once the data were adjusted to reflect the fact that severity of illness was on average higher among patients admitted to small units. These examples clearly demonstrate that in order to minimise bias in volume–outcome studies, account must be taken of any factors (beyond volume), that are likely to affect patient outcomes.

Results

Of the 36 studies identified in the search, 17 were concerned with CE, 16 considered AAA repair, and four were concerned with other vascular interventions, such as reconstructive surgery and amputation (note that one of the studies considered both CE and AAA[64]). All except one of the CE studies and all but three of the AAA studies were from the USA. The exceptional CE study was Finnish,[56] while for AAA the exceptions were one study each from Finland,[55] Norway[42] and the UK.[44] The four studies concerned with other vascular interventions were undertaken in Finland,[57] Sweden,[72] the UK[76] and the USA.[43]

CE. All 17 studies based their analysis on retrospective data derived from various hospital or administrative databases. The numbers of CEs carried out in the studies ranged from 508[40] to 113,300.[75]

The studies were categorised into three groups according to whether they made full adjustment, partial adjustment or no adjustment for casemix. Full adjustment is defined as adjusting for demographic factors, co-morbidity and severity/stage of illness. Studies were deemed to have considered severity/stage of illness if they separately identified asymptomatic and transient ischaemic attacks and amaurosis. Studies were defined as having made partial adjustment if they adjusted for demographics and co-morbidity but did not adjust for severity/stage of illness.

Of the 17 studies, three made no adjustment for casemix,[69–71] nine made partial adjustment,[40,46,48,49,52,62,64,68,75] and five made full adjustment.[53,54,56,60,65] Considering first the studies that made no adjustment, Richardson and Main[69] found statistically significant differences in postoperative stroke rates between surgeons performing fewer than three CEs per year and those performing more than 12 per year. A similar relationship was identified when outcome was defined as stroke, mortality and other complications combined. Ruby and co-workers[70] found a significant inverse relationship between physician volume and combined mortality/stroke rates. Finally, Segal and co-workers[71] found that physicians with an annual caseload of 15 or more CEs had a significantly lower mortality rate than physicians performing fewer than 15 CEs per year.

Of the nine studies that made partial adjustment for casemix, five focused on mortality only,[49,52,64,68,75] two considered mortality and stroke separately,[48,62] while two measured outcome in terms of combined mortality/stroke.[40,46] Among the first group, Wennberg and co-workers[75] found evidence of a statistically significant inverse relationship between hospital volume and mortality. This finding contrasts with that of Perler and co-workers,[68] where no such relationship was identified. The remaining three studies all report significantly lower mortality rates in high-volume hospitals.[49,52,64] However, different definitions of high volume were used in each study, with high annual caseload being defined as 20 or more,[64] more than 40[49] and more than 100.[52] The last of these studies also reports a significantly lower mortality rate among physicians performing five or more CEs per year. A significant positive volume–mortality relationship for physicians was also found by Edwards and co-workers,[48] but with different volume cut-off points. They report that physicians with an annual caseload of 12 or fewer CEs have a higher mortality rate than physicians who perform 50 or more CEs per year. These results contrast those of Mattos and co-workers[62] who found that there was no significant difference in mortality rates between physicians performing more or fewer than 12 CEs per year. They did, however, find that stroke rates were significantly lower among physicians whose annual caseload was more than 12 CEs. Edwards and co-workers[48] also found a significant inverse relationship between physician volume and stroke rates. However, when hospital volume was considered, no significant differences in stroke or mortality rates were found between high- and low-volume centres.

Of the two studies that considered combined stroke/mortality rates, AbuRahma and co-workers[40] found high-volume physicians (i.e. annual caseload greater than ten) had better outcomes than their low-volume counterparts. Cebul and co-workers[46] on the other hand found no difference in outcome between high- and low-volume physicians (defined as more or fewer than 21 CEs per year, respectively), but report better outcomes at high-volume hospitals (i.e. annual caseload greater than 62).

Of the five studies that made full adjustment for casemix, three measured outcome in terms of combined mortality/stroke rates,[53,54,56] one considered mortality and stroke separately,[60] and one focused on strokes only.[65] Neither of the last two studies found statistically significant evidence of a positive volume–outcome relationship at either the hospital or physician level. Statistically significant evidence supportive of such a relationship was reported in the other three studies.[53,54,56] Karp and co-workers[53] found that high-volume hospitals (annual caseload of at least 50 CEs) had better outcomes than low-volume hospitals (annual caseload of ten or fewer CEs). In contrast, Kantonen and co-workers[56] found no evidence of such a relationship. However, they did find that physicians performing more than ten CEs per year had better outcomes than those whose annual caseload was below ten. This finding is supported by Kucey and co-workers[54] who report that that medium-volume (between six and 12 CEs per year) and high-volume (more than 12 CEs annually) physicians had significantly better outcomes than their low-volume (fewer than six per year) counterparts.

The above results for CE are summarised in *Table 21*. It can be seen from this table that overall the weight of evidence is supportive of there being a positive volume–outcome relationship for both mortality and stroke at the physician level. There is slightly less support for a positive relationship for mortality at the hospital level, while the evidence for stroke is supportive of there being no benefits accruing to higher-volume hospitals. The picture changes, however, if consideration is restricted to only those studies that made full adjustment for casemix. Among these studies the statistically significant evidence for or against a positive volume–outcome relationship is more balanced with no clear support either way.

TABLE 21 *Summary of studies relating to CE*

Study	Definition of volume (annual caseload)		Statistically significant relationship identified?			
			Stroke		Mortality	
	Hospital	Physician	Hospital	Physician	Hospital	Physician
No adjustment for case-mix						
Richardson & Main, 1989[69]		< 3, > 12		Yes $p < 0.01$		Yes[a] $p < 0.001$
Segal *et al.*, 1993[71]	< 15, ≥ 15	< 15, ≥ 15			No $p = 0.082$	Yes $p < 0.01$
Ruby *et al.*, 1996[70]		< 1, 2–5, 6–10, > 10		Yes[b] $p < 0.01$		Yes[b] $p < 0.01$
Partial adjustment						
Fisher *et al.*, 1989[49]	≤ 40, > 40[c]				Yes $p < 0.05$	
Cebul *et al.*, 1998[46]	< 62, > 62	< 21, > 21	Yes[b] $p < 0.01$	No[b] $p = 0.47$	Yes[b] $p < 0.01$	No[b] $p = 0.47$
Wennberg *et al.*, 1998[75]	1–6, 7–21, > 21				Yes $p < 0.001$	
Manheim *et al.*, 1998[64]	< 20, ≥ 20				Yes $p < 0.01$	
Hannan *et al.*, 1998[52]	≤ 100, > 100	< 5, ≥ 5			Yes $p < 0.05$	Yes $p < 0.05$
AbuRahma *et al.*, 1988[40]		≤ 10, > 10		Yes[b] $p < 0.05$		Yes[b] $p < 0.05$
Edwards *et al.*, 1991[48]	≤ 12, ≥ 50	≤ 12, ≥ 50	No[d]	Yes $p < 0.01$	No[d]	Yes $p < 0.05$
Perler *et al.*, 1998[68]	≤ 10, 11–49, ≥ 50				No $p = 0.079$	
Mattos *et al.*, 1995[62]		≤ 12, > 12		Yes $p < 0.01$		No $p = 0.30$
Full adjustment						
Kempczinski *et al.*, 1986[60]	< 50, 50–100, > 100	< 12, 12–50, > 50	No $p > 0.05$	No $p > 0.05$	No $p > 0.05$	No $p > 0.05$
Mayo *et al.*, 1998[65]	2–28, 29–100	< 11, > 12	No[d]	No[d]		
Karp *et al.*, 1998[53]	≤ 10, ≥ 50		Yes[b] $p < 0.05$		Yes[b] $p < 0.05$	
Kucey *et al.*, 1998[54]		< 6, 6–12, > 12		Yes[b*]		Yes[b*]
Kantonen *et al.*, 1998[56]	Not defined	≤ 10, > 10	No[b,d]	Yes[b] $p < 0.01$	No[b,d]	Yes[b] $p < 0.01$

[a] *Mortality/stroke/other complications combined*
[b] *Mortality/stroke combined*
[c] *15-month time period*
[d] *No p-values given*
[*] $p < 0.05$ *when comparing < 6 per year with 6–12 per year;* $p < 0.01$ *when comparing < 6 per year with > 12 per year*

AAA repair. Fourteen of the 16 studies investigating the impact of volume on the outcome of AAA repair used retrospective data derived from various hospital or administrative databases. The two remaining studies are unique among the 36 studies identified in the review in that they used a prospective design.[42,44] The samples involved in the AAA studies ranged from 243 patients[67] to over 10,000 operations.[58]

All but one of the studies made adjustment for demographic factors and co-morbidity, the exception being Berridge and co-workers.[44] Studies were deemed to have adjusted for severity/stage of illness if they reported results separately for ruptured and unruptured aneurysms. Of the 16 studies, four failed to do this.[45,59,61,63] Two of these did not report any significance values to support their findings,[61,63] and the findings of the other two studies contrast each other.[45,59] Specifically, Burns and Wholey[45] report a significant negative correlation between mortality and volume for physicians but not for the hospital, while Kelly and Hellinger[59] found that lower mortality was significantly associated with higher-volume hospitals but not higher-volume surgeons.

Two of the studies that adjusted for severity of illness considered only ruptured aneurysms.[47,67] Ouriel and co-workers[67] found no significant evidence of lower mortality for high-volume surgeons (performing more than two procedures per year) compared with their low-volume counterparts (averaging two or fewer per year). In contrast, Dardik and co-workers[47] found that patients who were operated on by high-volume surgeons had significantly lower postoperative mortality rates. No such relationship was found when hospital volume was considered.

Three further studies considered only unruptured aneurysms.[41,50,73] Despite having different definitions of high and low volume, two of these report significantly lower mortality among both high-volume hospitals and physicians.[50,73] Hannan and co-workers[50] defined low and high volume as more or fewer than 20 procedures annually for hospitals and an annual caseload of more or fewer than four procedures for physicians. This contrasts with Veith and co-workers[73] who defined low and high annual hospital volume as five or fewer and more than 38 procedures, respectively. For physicians, the corresponding low- and high-volume figures were five or fewer and more than 26. The third study found no evidence of a positive volume–outcome relationship at the physician level, but did not define volume beyond 'high' and 'low'.[41]

The remaining seven studies each report results for both ruptured and unruptured aneurysms.[42,44,51,55,58,64,74] Of these, Berridge and co-workers[44] did not report significance levels for their results, nor, it should be reiterated, did they make any adjustments for casemix differences. Five of the remaining six studies found evidence of a significant positive volume–mortality relationship for unruptured aneurysms at the hospital level, the exception being Kantonen and co-workers.[55] Definitions of high and low hospital volume included annual caseloads of more or fewer than ten,[42] more or fewer than 21[58] and more or fewer than 50.[64] The other three studies defined volume as a continuous variable in multiple regression analyses.[51,55,74]

When consideration was given to ruptured aneurysm, four of the six studies found no evidence of a significant volume–mortality relationship at the hospital level.[42,51,55,74] The exceptions here were the studies by Katz and co-workers[58] and Manheim and co-workers.[64] Of the studies that investigated the effects of physician volume on mortality, Kantonen and co-workers[55] found evidence of a significant positive relationship for unruptured aneurysms but not for ruptured, while the reverse of these results was reported by Hannan and co-workers.[50]

The above results for AAA repair are summarised in *Table 22*. It can be seen from this table that there is evidence of a positive volume–outcome relationship existing for unruptured aneurysms at both the physician and hospital level, with the evidence being particularly strong at the level of the hospital. For ruptured aneurysms, the weight of evidence from the studies is suggestive of there not being a positive volume–outcome relationship at the hospital level, while at the physician level the evidence is more balanced with no clear support either way.

Other vascular interventions. In addition to the CE and AAA papers, four studies were identified that focused on volume–outcome issues for other vascular interventions.[43,57,66,72] The study by Troeng and co-workers[72] focused on chronic ischaemia of the leg and measured outcome in terms of mortality and morbidity at 30 days, 1 year and 1000 days. The results, which were adjusted for demographics and comorbidity, but not stage of illness, indicated that physician volume was not an important factor in determining patient outcome.

***TABLE 22** Summary of results for AAA repair*

Study	Definition of volume (annual caseload)		Statistically significant relationship identified?			
			Ruptured		Unruptured	
	Hospital	Physician	Hospital	Physician	Hospital	Physician
Hannan *et al.*, 1989[50]	≤ 20, > 20	≤ 4, > 4			Yes[a] $p < 0.05$	Yes $p < 0.05$
Ouriel *et al.*, 1990[67]		≤ 2, > 2		No $p > 0.10$		
Veith *et al.*, 1991[73]	1–5, > 38	1–5, > 26			Yes $p < 0.001$	Yes $p < 0.001$
AbuRahma *et al.*, 1991[41]		'high' and 'low'				No $p > 0.05$
Dardik *et al.*, 1998[47]	< 10, 10–19, ≥ 20[b]	1–4, 5–9, ≥ 10[b]	No $p = 0.80$	Yes $p < 0.05$		
Amundsen *et al.*, 1990[42]	< 10, > 10		No $p = 0.14$		Yes $p < 0.05$	
Hannan *et al.*, 1992[51]	Continuous[c]	Continuous[c]	No $p > 0.05$	Yes $p < 0.001$	Yes $p < 0.01$	No $p > 0.05$
Katz *et al.*, 1994[58]	< 5, ≥ 5[d], < 21, ≥ 21[a]		Yes $p < 0.01$		Yes $p < 0.01$	
Wen *et al.*, 1996[74]	Continuous[c]		No $p > 0.05$		Yes $p < 0.05$	
Kantonen *et al.*, 1997[55]	Continuous[c]	Continuous[c]	No $p > 0.05$	No $p > 0.05$	No $p > 0.05$	Yes $p < 0.01$
Manheim *et al.*, 1998[64]	< 50, ≥ 50		Yes $p < 0.001$		Yes $p < 0.05$	

[a] Unruptured aneurysms
[b] 6-year time period
[c] Volume defined as a continuous variable in multiple regression analysis
[d] Ruptured aneurysms

Note. The studies by Kelly & Hellinger,[59] Maerki et al.*,[63] Luft* et al.*,[61] and Burns & Wholey[45] are not included in the above table as they did not report results separately for ruptured and unruptured aneurysms. The study by Berridge* et al.*,[44] is not included because no tests of statistical significance were reported*

These results contrast those of Kantonen and co-workers[57] who were concerned with the treatment of chronic critical leg ischaemia. Having made full adjustment for casemix differences, they concluded that low-volume physicians and hospitals (fewer than ten and 20 procedures per annum, respectively) had significantly higher amputation rates than their high-volume counterparts, but that there was no difference in 30-day mortality rate.

An association between amputation rates and volume was also reported by Michaels and co-workers.[76] Following an audit of vascular surgical practice in the Oxfordshire region in the UK, they found that high-volume districts had significantly lower amputation rates than low-volume districts. However, no apparent adjustments for casemix differences were made.

Amputation rates were also investigated by Bates and co-workers.[43] Using fully adjusted data, they found no evidence of a statistically significant relationship between the rate of above-knee amputation and 30-day mortality at hospital level.

Discussion and conclusions

The systematic review reported above identified 36 articles that investigated the possibility of there being a positive relationship between the volume of procedures performed in peripheral vascular surgery and the resultant health outcomes. Of the 36 studies identified, 17 focused on CE, 16 were concerned with AAA repair, and four were concerned with other vascular interventions.

For the 'other vascular interventions' there was an insufficient number of studies upon which to formulate any meaningful conclusions. When taken together, the CE studies are supportive of a positive volume–outcome relationship existing at the physician level for both mortality and stroke. However, the weight of evidence becomes less conclusive when consideration is restricted to those studies that made full adjustment for casemix. For unruptured AAAs, the evidence would seem to support the existence of a positive volume–outcome relationship at both the physician and hospital level. The weight of evidence was particularly strong at the hospital level. For ruptured aneurysms, on the other hand, the weight of evidence is against there being a positive volume–outcome relationship at the hospital level, while for physicians there was no clear support either way.

Having synthesised the results of the studies identified in the review, it is worth highlighting a number of points that should be considered in connection with volume–outcome studies more generally. Chief among these is the importance of adjusting for differences in casemix. As already discussed above, failure to do so can lead to misleading and biased results.

Another potential problem arises from the predominant use of mortality as the principal measure of outcome in the volume–outcome studies. A potential drawback with using mortality is that the measure generally refers to death occurring during an inpatient stay. In many cases, deaths occurring after discharge are usually not included. It follows, therefore, that mortality may be a reasonable measure of short-term outcome, but is likely to be a poor measure of outcome in the longer term. Even if consideration is restricted to the short term, problems may still arise from using mortality as an outcome measure. These stem from the fact that inpatient mortality is likely to be affected by differences in patient discharge policies between surgeons or hospitals. If adjustment is not made for different policies, then it is possible that differences in outcomes may be attributable to different patient management strategies rather than differences in outcomes *per se*.

Few studies attempted to measure morbidity and none measured QoL. This may have been due to mortality being regarded as the measure of overriding importance with CE and AAA repair. Alternatively, it may have been due (at least in part) to the fact that all but two of the studies were based on retrospective data where measures of QoL tend not to be routinely recorded. Prospective studies allow data on QoL to be collected and also allow mortality data after discharge to be recorded. Other things being equal, prospective studies provide richer data sets than retrospective studies, and as such it can be argued that there is a need for more prospective studies to investigate volume–outcome relationships. While the ideal would be randomised trials, it would be difficult to undertake these in this context and therefore detailed prospective cohort studies may be the best pragmatic option.

Regardless of whether or not the study is retrospective or prospective, problems can still arise when trying to draw conclusions from volume–outcome studies if there is no consensus as to what constitutes low and high volume. It can be clearly seen from *Tables 21* and *22* that definitions of what constitutes high and low volume varied considerably among the CE and AAA studies. Such variability in definitions makes it difficult to draw meaningful comparisons between studies dealing with the same procedure.

In conducting the systematic review and synthesising the existing evidence on volume–outcome relationships in peripheral vascular surgery, we have highlighted circumstances where there may or may not be scope for improving outcomes by increasing volume. However, it is possible that our conclusions may be attributable to factors such as lack of adjustment for casemix, different definitions of volume and poor quality of studies, particularly those of retrospective design. We recommend that future studies should address these deficiencies by making **full adjustment for casemix** and by being **prospective in design**.

There can be no doubt that establishing whether or not positive volume–outcome relationships exist in peripheral vascular surgery has important implications for the organisation of such services. The current situation in many countries is that vascular surgery has developed gradually following sub-specialisation by general surgeons. This has resulted in a service with many small units where the vascular specialists deal with relatively small volumes, but also assist in providing a general surgical service. Such arrangements are common in many countries. For example, a recent study from Finland showed that of 104 surgeons carrying out CE, only ten of them carried out more than ten procedures in a single year, while 20 of them carried out only a single procedure annually.[56] Similarly, a study from California showed that approximately 50% of elective aortic aneurysm repairs were carried out in centres with a volume of fewer than 20 procedures per year.[64] In the UK, a recent Vascular Surgical Society audit showed that the median number of femoro-distal bypasses and CEs that a surgeon carried out each year was ten and 15, respectively.[77]

The management of acute ischaemia

Over recent years there have been a number of developments in the treatment of acute limb ischaemia. In particular the use of thrombolysis may have profound implications for the organisation of vascular services. Thrombolysis involves the use of a thrombolytic agent to breakdown the fibrin contained within a thrombus.[78] The three most commonly used substances are streptokinase, urokinase and (recombinant) tissue plasminogen activator (rt-PA). The mode of action of all them involves the utilisation of a proenzyme, plasminogen, which is converted to an active thrombolytic enzyme, plasmin, which breaks down fibrin.[79]

Thrombolysis has been used as a treatment for acute arterial and graft occlusions for over 30 years but until the last 10 years there were no RCTs to support its use.[80] Thrombolysis allows the option of restoring blood flow with only a mildly invasive technique.[81] However, treatment is relatively expensive in terms of costs and resources.[82]

Despite the advantages of thrombolysis there are still doubts regarding its safety and efficacy as there are risks of haemorrhage and the time to recanalise the affected artery is relatively long compared with surgical intervention.[83] There are also few data on the cost-effectiveness of thrombolysis compared with surgery with only two studies, both carried out in the USA, and both using hospital cost data.[84,85]

This was felt to be a key area for analysis as it requires the availability of emergency radiology facilities with a high level of equipment and radiological staff with the necessary technical expertise. If this proves to be a highly cost-effective development then it is likely to have a significant effect on the configuration of services.

Local data

It is not possible to separately identify patients admitted for acute lower limb ischaemia from routine data as there is no separate diagnostic code that is used consistently and the condition is not associated with unique procedures. It is also impossible to identify episodes of intra-arterial thrombolysis, as it is not specifically coded in the OPCS system. However, the interviews with consultants in the different districts showed that there are differences in the management of acute ischaemia, particularly in respect of the preference for use of thrombolysis. A linked issue is that only the teaching centre has a formal on-call rota for specialist vascular radiologists. A systematic literature review of published data has looked at the use of intra-arterial thrombolysis for acute lower limb ischaemia to consider whether it has any proven benefits, and if so to quantify these.

Published data

A systematic literature review has been carried out to assess the existing evidence relating to the efficacy and cost-effectiveness of intra-arterial thrombolysis for acute ischaemia.

Methods

A search of major databases for RCTs related to thrombolysis was undertaken. The search was limited to English language articles or articles that provided a sufficiently detailed English summary of trial design and results. There was no restriction as to the years searched or country of origin of the trials. The full search strategy is given in appendix 2. Handsearching of core journals and review of citations were also performed following guidelines developed by the Baltimore Cochrane Centre.[86]

Trials were considered for inclusion if they were prospective RCTs evaluating thrombolytic therapy. The quality of a trial was determined using a proforma based on the CONSORT statement[87] and Cochrane Collaboration checklists.[86] The proforma graded studies for inclusion by assessment of:

- method of randomisation and degree of blinding
- comparability of groups in control and intervention arms at baseline
- the analysis of results on an intention-to-treat (ITT) basis
- completeness of follow-up
- the blinding and objectivity of outcome assessment
- the appropriateness and completeness of statistical analysis of results, including sensitivity analysis.

Data were extracted independently by two reviewers and cross-checked for accuracy. Aggregate outcomes were obtained using a random-effects meta-analysis.

Results

A total of 34 papers were identified, and of these ten were found to be RCTs (see appendix 3). A summary of the methodological quality of these papers is given in *Table 23*. The other papers were either review articles, case series or cohort studies and were, therefore, excluded[78,79,84,85,88–105] (*Table 24*).

Description of studies

Surgery versus thrombolysis. There were seven papers published that randomised patients to either surgery or thrombolysis. The largest studies were the Surgery versus Thrombolysis for Ischemia of the Lower Extremity (STILE) trial[106] and Thrombolysis or Peripheral Arterial Surgery (TOPAS) Phase I[81] and II.[83]

TABLE 23 *Methodological quality of included studies*

	Clear inclusion/ exclusion criteria	Sample size	Method of randomisation	Blinding of treatment allocation	Comparable groups at start of trial	Blinded outcome assessment	ITT analysis
Graor *et al.*, 1994[106] (STILE trial)	✔	Estimated sample size 1000 patients but terminated at 393	Central randomisation centre	✔	✔	Not stated	✔
Comerota *et al.*, 1996[111] (Report of sub-group of STILE trial: occluded grafts)	✔	124	Central randomisation centre	✔	✔	Not stated	✔
Weaver *et al.*, 1996[107] (Report of sub-group of STILE trial: native artery occlusions)	✔	237	Central randomisation centre	✔	✔	Not stated	✔
Ouriel *et al.*, 1996[81] (TOPAS Phase I)	✔	213	Central randomisation centre	✔	✔	Not stated	✔
Ouriel *et al.*, 1994[108]	✔	114	Randomisation cards and opaque envelopes	✔	✔	Not stated	✔
Ouriel *et al.*, 1998[83] (TOPAS Phase II)	✔	544	Central randomisation centre	✔	✔	Not stated	✔
Berridge *et al.*, 1991[110]	✔	60	Not stated	Unclear	✔	Not stated	✔
Braithwaite *et al.*, 1997[80]	✔	100	Not stated	Unclear	✔	Not stated	✘

The STILE trial randomised a total of 393 patients to either surgical revascularisation or rt-PA or urokinase in a multicentre trial carried out in the USA. The initial design was for 1000 patients but enrolment stopped after the interim analysis because a significant primary endpoint was reached when the results were analysed.

The primary endpoint was a 'composite clinical outcome', which was defined as the occurrence of an adverse event. These events ranged in severity from death/major amputation to post-interventional wound complications. There was also separate reporting of mortality, amputation, ischaemia and life-threatening haemorrhage. Analysis was by ITT and so failure to place the catheter for thrombolysis in 28% of patients was considered a failure of treatment.

Results showed that in the thrombolysis group there was greater risk at 1-month post-treatment of:

- composite clinical outcome (55.2% ($n = 107$) versus 34.6% ($n = 44$); $p < 0.001$)
- ongoing/recurrent ischaemia (45.4% ($n = 88$) versus 23.6% ($n = 30$); $p < 0.001$)

TABLE 24 *Excluded studies*

Published trial	Reason for exclusion
Allen *et al.*, 1992[88]	Review article
Braithwaite *et al.*, 1996[89]	Review article
Dawson *et al.*, 1991[90]	Retrospective study
De-Felice *et al.*, 1990[91]	Review article
Diffin & Kandarpa, 1996[92]	Review article
Earnshaw *et al.*, 1987[93]	Retrospective cohort study
Earnshaw, 1994[94]	Review article
Earnshaw, 1991[95]	Review article
Gaines *et al.*, 1991[79]	Review article
Golledge & Galland, 1995[78]	Review article
Gonzalez-Fajardo *et al.*, 1995[96]	Non-randomised study
Goodman *et al.*, 1993[97]	Cohort study
Hess *et al.*, 1996[98]	Non-randomised study
Hicken *et al.,* 1995[99]	Cohort study
Hye *et al.*, 1994[100]	Retrospective study
Marcus & Bearn, 1996[101]	Cohort study
Meyerovitz *et al.,* 1990[102]	Small study (16 patients), methodological problems
Ouriel *et al.*, 1995[85]	Economic study
Ouriel, 1995[103]	Report of Ouriel[81]
Ouriel, 1996[104]	Review article
Pilger, 1996[105]	Review article
Van Breda *et al.*, 100[184]	Economic study

- life-threatening haemorrhage (6.2% ($n = 12$) versus 0.8% ($n = 1$); $p = 0.019$)
- vascular complication (11.3% ($n = 22$) versus 3.1% ($n = 4$); $p = 0.01$).

The mean length of hospital stay was less in the thrombolysis group (9.7 versus 14.3 days; $p = 0.04$). However, there was no statistically significant difference between the two groups in terms of mortality ($p = 0.38$) or major amputation ($p = 0.726$).

The study also carried out subgroup analysis on the basis of duration of ischaemia. At 1-month follow-up patients with ischaemia of greater than 14 days in the thrombolysis group had a greater risk of composite clinical outcome (62.9% ($n = 107$) versus 29.2% ($n = 28$); $p < 0.001$)) and ongoing recurrent ischaemia (58.2% ($n = 99$) versus 20.8% ($n = 20$); $p < 0.001$). However, with ischaemia of less that 14 days duration there were no statistically significant differences between surgery and thrombolysis groups.

The 6-month follow-up confirmed the benefits of thrombolysis for patients with ischaemia of less that 14 days with a greater risk of major amputation in the surgery group (30% ($n = 12$) versus 11.1% ($n = 8$); $p = 0.02$).

There was also a higher risk of major amputation in the thrombolysis group (12.1% ($n = 21$) versus 3% ($n = 3$); $p = 0.01$) for those with ischaemia of greater than 14 days.

One paper[111] reported the subgroup of patients who had occluded by-pass grafts in the STILE trial.[106] All outcomes were at 1-year follow-up. Prosthetic grafts tended to have increased 'major morbidity' compared with autogenous grafts ($p = 0.04$). There was confirmation of the benefit of thrombolysis for acute ischaemia with an increased risk of major amputation in surgery arm of trial (48% ($n = 11$) versus 20% ($n = 7$); $p = 0.026$). However, there were no statistically significant differences between the groups for those with chronic ischaemia.

A second subgroup of patients with non-embolic native artery occlusions were reported from the STILE trial.[107] This suggested that surgery was more effective than thrombolysis. There was an increased risk of major amputation at 6 months in the thrombolysis group (6.7% ($n = 10$) versus 0%; $p < 0.05$) and 1 year (10% ($n = 15$) versus 0%; $p < 0.05$). This was particularly pronounced in the subgroup with femoral-popliteal artery occlusions with a greater risk of amputation with thrombolysis at 6 months (8.7% ($n = 9$) versus 0%; $p < 0.005$) and 1 year (13.5% ($n = 14$) versus 0%; $p = 0.001$). In addition, patients with diabetes in the femoral-popliteal artery occlusion group who had surgical revascularisation had a higher mortality rate at 30 days (16% versus 0%; $p = 0.005$), 6 months (25.8% versus 1.9%; $p = 0.002$) and 1 year (32% versus 6%; $p = 0.014$).

A total of 213 patients were randomised to intra-arterial variable doses (2000 IU or 4000 IU or 6000 IU) of r-urokinase or surgery in the TOPAS Phase I trial.[81] There were no statistically significant differences between surgery and thrombolysis groups in terms of mortality, amputation-free survival or incidence of haemorrhage. However, the higher dose of urokinase (6000 IU) did experience more haemorrhagic complications when compared with the other dosages ($p = 0.031$).

The TOPAS Phase II trial was a multicentre trial and randomised 548 patients with acute limb ischaemia to either intra-arterial urokinase or surgery.[83] There were some demographic differences at baseline: the thrombolytic group had significantly more men ($p = 0.046$), patients with rest pain ($p = 0.003$) and patients with hepatic and renal insufficiency ($p = 0.027$). There were no statistically significant differences in amputation-free survival or mortality between thrombolysis and surgery groups at 6 months and 1 year. In addition, there were no differences between the two groups in length of stay (median 10 days for both groups) or ankle/brachial pressure index ($p = 0.23$) (see appendix 3). There was, however, an increased risk of major haemorrhagic complications in the thrombolysis group (12.5% ($n = 32$) versus 5.5% ($n = 14$); $p = 0.005$) and a significant association between risk of haemorrhage and co-administration of heparin (relative risk (RR), 2.19; $p = 0.02$; 95% CI, 1.13 to 4.24).

A total of 119 patients were randomised in a single centre trial performed in the USA,[108] with analysis being carried out for 114. Patients with less than 7 days' duration of ischaemia were randomised to either intra-arterial thrombolysis or surgery. The treatment groups were 'balanced' at baseline. The 30-day combined mortality or amputation was greater in the surgical group (30% ($n = 17$) versus 14% ($n = 8$); $p = 0.04$). However, there was no significant difference in separate mortality and amputation rates. Kaplan-Meier estimate of event-free survival yielded a risk of limb loss or death for thrombolysis of 25% versus 48% for surgery ($p = 0.02$). There was also a 62% reduction in the risk of death for the thrombolytic group (survival was 84% for thrombolysis versus 58% for surgery; $p = 0.01$).

A small single-centre study with only 20 patients randomised to either surgery (thrombectomy; $n = 9$) or thrombolysis (intra-arterial rt-PA; $n = 11$) reported no difference between the two groups in the rates of successful revascularisation.[109] There were no cases of mortality or major haemorrhage.

Mode of administration. There was only one study identified that examined mode of administration.[110] Sixty patients were randomised to either intra-arterial streptokinase or intra-arterial rt-PA or intravenous rt-PA. The trial was multicentred but no details of number or location of the centres was given in the paper. Intra-arterial rt-PA achieved greater complete or partial success than the other groups ($p < 0.04$). However, both intra-arterial rt-PA and intra-arterial streptokinase achieved complete success in 85% ($n = 17$) and 80% ($n = 16$), respectively, compared with only 30% ($n = 6$) for intravenous rt-PA. The difference between the groups in 3-month limb salvage rate did not achieve statistical significance.

Type of thrombolytic agent. Only one trial was found that directly compared two thrombolytic agents.[102] The sample size was small with 16 randomised to either intra-arterial rt-PA or urokinase. The main outcome measure was 95% or greater thrombolysis as determined by serial arteriograms at 4, 8, 16 and 24 hours. The trial found statistical significance ($p = 0.04$) at 8 hours in successful lysis in the rt-PA group, but not at the other time points. There was no significant difference between the groups in terms of clinical outcome.

This trial scored poorly on quality criteria. The analysis was not ITT and the number of patients whom had arteriograms varied at the different time points. For example, the initial number of 16 in each treatment arm became ten in the rt-PA group and 11 in the urokinase group at 8 hours, at 16 hours it was one in the rt-PA and four in the urokinase group, and at 24 hours it was five in the rt-PA and ten in the urokinase group. This may have lead to selection bias.

Dosage of thrombolytic agent. One trial compared dosage levels.[80] This was a multicentre trial carried out in the UK that randomised 100 patients with acute leg ischaemia of less than 30 days' duration, to intra-arterial thrombolysis with either high-dose bolus rt-PA (3 × 5 mg bolus doses then 3.5 mg/h for up to 4 hours and then 0.5–1.0 mg/h) or low-dose rt-PA (0.5–1.0 mg/h). Analysis was not by ITT as seven cases were excluded post-randomisation due to violation of protocol.

There were no statistically significant differences between the two groups in terms of 30-day limb salvage or complication rates. However, the patients in the high-dose group had more adjunctive procedures and vascular reconstructions (26 versus 16; $p = 0.002$).

Meta-analysis results

Aggregate outcomes were obtained using a random-effects method of meta-analysis. This method takes into account possible intra- and inter-study heterogeneity. Heterogeneity was tested using chi-square at a significance level of $p < 0.1$ due to the relative insensitivity of this test method.

All of the meta-analysis plots for thrombolysis versus surgery show that there appeared to be no difference between surgery and thrombolysis in terms of mortality and amputation. However, the aggregate odds ratio for major haemorrhage showed an increased risk for thrombolysis of 195% (odds ratio, 2.95; $p < 0.001$; 95% CI, 1.62 to 5.36).

Discussion

The results of the literature search have highlighted the lack of large RCTs evaluating thrombolysis versus surgical management. The two largest trials in this area are the STILE[106] and the TOPAS[81,83] trials. The RRs and numbers needed to benefit or harm (NNB or NNH) for the key findings of the published articles are shown in *Table 25*.

The STILE trial[106] showed that there was no difference between surgery and thrombolysis in terms of mortality or risk of amputation. However, it did show that there was an increased risk within the thrombolysis group as a whole of morbidity (RR, 1.70; 95% CI, 1.34 to 2.16), ongoing/recurrent ischaemia (RR, 2.1; 95%CI, 1.55 to 2.83) and haemorrhage (RR, 8.1; 95% CI, 1.10 to 60.96), when compared with surgery. However, subgroup analysis by duration of ischaemia showed that for ischaemia of less than 14 days the RR of mortality and/or amputation for the thrombolysis group compared with surgery was 0.41 (i.e. there was a 59% greater chance of mortality/amputation for the surgical group).

There were two other subgroups analysed within the STILE trial, native and graft occlusions. For native artery occlusions the analysis showed that

TABLE 25 RR, NNB and NNH (95% CI) for thrombolysis compared with surgery

Trial	RR	RR reduction	NNH/NNB
STILE trial [106]			
Composite clinical outcome (1 month)	1.70 (1.34 to 2.16)	–66%	NNH = 4 (3 to 6)
Recurrent ischaemia (1 month)	2.1 (1.55 to 2.83)	–110%	NNH = 4 (4 to 5)
6 month			
Mortality/amputation	0.98 (0.62 to 1.53)	2%	NNB = 204 (–13 to 13)
Amputation – ischaemia < 14 days	0.37 (0.17 to 0.83)	72%	NNB = 5 (3 to 35)
Amputation – ischaemia > 14 days	4.06 (1.24 to 13.29)	–306%	NNH = 12 (7 to 37)
Subgroup occluded grafts			
Composite clinical outcome (1 month)	1.8 (1.34 to 2.42)	–80%	NNH = 4 (3 to 33)
Ongoing/recurrent ischaemia (1 month)	1.7 (1.06 to 2.81)	–46%	NNH = 5 (3 to 21)
Duration of ischaemia < 14 days			
Major amputation (1 year)	0.42 (0.20 to 0.92)	58%	NNB = 3 (2 to 25)
Duration of ischaemia > 14 days			
Major amputation (1 year)	1.2 (0.35 to 4.27)	20%	NNH = 100 (–7 to 6)
Duration of ischaemia < 14 days			
Ongoing/recurrent ischaemia (1 month)	1.98 (1.77 to 3.34)	–98%	NNH = 3 (2 to 6)
Subgroup native artery occlusions			
Composite clinical cutcome	1.8 (1.34 to 2.42)	–80%	NNH = 4 (3 to 6)
Major amputation (6 months)	23.8 (0.46 to 1249.40)		NNH = 16 (8 to 50)
Major amputation (1 year)	35.4 (0.4 to 2657)	–354%	NNH = 10 (7 to 20)
Ongoing recurrent ischaemia	2.3 (1.60 to 3.42)	–130%	NNH = 3 (2 to 5)
TOPAS II [83]			
Major haemorrhagic complications	2.29 (1.25 to 4.20)	–129%	NNH = 14 (10 to 50)
***Ouriel* et al.** [67]			
Mortality (6 months)	0.74 (0.52 to 1.06)	53%	NNB = 10 (–4 to 14)
Mortality (12 months)	0.74 (0.2 to 2.7)	53%	NNB = 6 (–3 to 50)

there was a greater risk of major amputation in the thrombolysis group; except for patients with iliac-common femoral artery occlusions where there was no difference between surgery and thrombolysis.[107] For graft occlusions, thrombolysis increased the risk of ongoing/recurrent ischaemia (RR, 1.46) but there were no differences between the groups in terms of mortality or amputation rates.[111] The exception to this were patients with ischaemia of less than 14 days who had a greater risk of amputation in the surgical group (RR, 0.42), with thrombolysis showing an RR reduction for amputation of 58%.

The TOPAS Phase I study[81] appeared to show that the dosage of urokinase with the least risk haemorrhage was 4000 IU/minute. There were no significant differences between the different dosages and surgery in terms of mortality and amputation. The TOPAS Phase II study[83] found no differences between surgery and thrombolysis in terms of amputation, mortality, length of stay, and ankle/brachial pressure index; but there was a greater risk of haemorrhage in the thrombolysis group (RR, 2.29; 95% CI, 1.3 to 4.2). There also appeared to be an increased risk of haemorrhage with the therapeutic use of heparin (RR, 2.19; $p = 0.02$; 95% CI, 1.13 to 4.24).

Both the STILE and TOPAS trials have some methodological flaws. The STILE trial originally aimed to recruit 1000 patients based on sample size calculations but recruitment was stopped after 393 due to a "significant primary endpoint occurring at the interim analysis". This could mean that the trial's power will be reduced in detecting significant differences, particularly within the subgroup analysis. In addition, thrombolysis patients were randomised to either rt-PA or urokinase but the results for thrombolysis were analysed by pooling these two groups. The TOPAS Phase II study's main flaw was the large number of centres contributing to the study compared with the total number of patients included in the study: there were 113 centres involved in the study and 548 patients recruited. The limited number of patients recruited at each centre could indicate selection bias or recruitment problems. Furthermore, such a large number of centres with resultant variations in practice and setting means that there could be doubts about the external validity of the trial.

Ouriel and co-workers[108] found that there was a decreased risk of amputation or death at 1 year in the thrombolysis group (RR, 0.47) and the cumulative survival rate was greater in the thrombolysis group. However, this study only included acute limb ischaemia of less than 7 days. It does appear to confirm the benefits of thrombolysis for patients with limb ischaemia of short duration. Nilsson and co-workers[109] reported a small study of only 20 patients and failed to detect any significant differences between surgery and thrombolysis, most probably due to an inadequate sample size. Berridge and co-workers[110] achieved greater success with intra-arterial administration at the site of the thrombus rather than systemic intravenous administration. However, the trial was relatively small ($n = 60$) and the sample size was probably insufficient to detect differences between the two groups on all the outcome measures included.

Braithwaite and co-workers[80] compared high-dose and conventional low-dose regimens for intra-arterial rt-PA administration. The trial suggested benefits of the high dose in terms of reduced duration of infusion but there were a greater number of adjunctive procedures compared with the low-dose group. However, the trial did not analyse by ITT and the study admits to not having sufficient power.

These results suggest that thrombolysis does not provide benefit for the whole patient population presenting with limb ischaemia. The trials suggest that there could be subgroups of patients who would benefit from thrombolysis compared with surgery. The patients who would benefit the most are all those with acute ischaemia of less than 14 days' duration (NNB, 5; 95% CI, 3 to 35) and those with acute by-pass graft occlusions (NNB, 3; 95% CI, 2 to 25). However, it should be noted that the CIs for the NNB are relatively wide.

In addition, there are groups where thrombolysis should be avoided. There was an increased risk of amputation for chronic ischaemia (NNH, 12; 95% CI, 7 to 37) and chronic graft occlusions showed an increased risk of ongoing recurrent ischaemia (NNH, 3; 95% CI, 2 to 6).

However, the conclusion of harm or benefit are based on subgroup analysis within the participants of the trial and so should not be classified as definitive as the sample sizes in some of the groups were relatively small and, therefore, have reduced power to detect differences.

The nature of leg ischaemia means that the best results of treatment are likely to be in centres with a high workload,[112] offering a full range of services with cooperation between vascular surgeons and radiologists.[113] The risks and benefits of thrombolysis have to be assessed by surgeons, radiologists and patients as thrombolysis appears to be of benefit to a small subgroup of the whole population of patients with limb ischaemia. If thrombolysis is attempted and is not successful then there needs to be facilities and expertise for other treatment options.

Conclusion

The main conclusion to be drawn from the trials is that thrombolysis should not be given to every patient who presents with lower limb ischaemia and should be viewed as an adjunct to other treatments. The specific subgroups of patients who may derive the most benefit from thrombolysis are patients with acute ischaemia and graft occlusions of less than 14 days. Thrombolysis should be avoided in other groups. This includes those with chronic graft occlusions, chronic ischaemia and native artery occlusions. However, these conclusions are based on subgroup analysis and new trials are urgently required that have sufficient sample size, QoL data and economic analysis, to confirm or refute these results.

In terms of the implications for the organisation of vascular services it would seem that the current evidence for any benefit from thrombolysis is not strong, and it should not, therefore, be a major consideration in organising services. It is, however, clear that its use requires the availability of a multidisciplinary team with the appropriate skills, and that, if offered, the service needs appropriate out-of-hours support.

Carotid endarterectomy

Local data

The most important outcomes following carotid surgery are mortality and major cerebrovascular events. Unfortunately, the latter are not identifiable from routinely collected data.

The overall mortality for Sheffield is 0.56%, which is below the mortality rates reported in the large multicentre trials. Other hospitals in North Trent do not have sufficient throughput to make a reasonable estimate of mortality.

Potentially the length of stay could be used as a proxy indicator of outcome, as patients who suffer from major cerebrovascular events may have delayed discharge. In practice this does not produce consistent results as some patients are treated in the convalescent period after a recovered cerebrovascular accident and in these cases delayed discharge may be unrelated to surgical complications. Conversely, patients who suffer a postoperative cerebrovascular event may be transferred to the care of a physician, neurologist or rehabilitation unit.

A major issue in respect of CE would appear to be the large differences in rates for the procedure. Such differences are consistent with those reported elsewhere.[29] This may be expected to have implications for outcome, but there is no way of identifying those patients who would have been suitable for CE. There are numerous other factors that affect the overall rate of stroke, and it is difficult to see how the impact of differences in provision could be quantified, other than by extrapolation from published data.

Published data

Due to the limitation of resources it was not possible to carry out a full systematic review of CE. However, there were known to be a number of large multicentre RCTs and an existing Cochrane systematic review related to the subject and the results of these are summarised below.

Symptomatic carotid stenosis

There have been two large RCTs that have evaluated the benefits of carrying out CE on symptomatic patients, that is those patients who have had transient ischaemic attacks, non-disabling stroke, amaurosis or retinal infarction, and who had either severe or mild carotid stenosis. One trial evaluated the benefits in patients with moderate symptomatic stenosis.

- The Medical Research Council European Carotid Surgery Trial (MRC ECST) randomised 2518 patients with severe (70% to 99%) and 1599 patients with moderate (40% to 69%) stenosis. These arms of the trial were reported separately.[114,115]
- The North American Symptomatic Carotid Endarterectomy Trial (NASCET) randomised 659 patients to immediate surgery or no immediate surgery.[116]

MRC ECST.[114,115] For patients with severe stenosis, the incidence of death or 'disabling or fatal' strokes was 3.7% within 30 days of surgery. When comparing surgery with non-surgery there was a significant eight-fold reduction ($p < 0.0001$) in ipsilateral ischaemic strokes (5/455 versus 37/323) within 36 months. However, the absolute difference, including contralateral stroke, was not as marked, with a 5% difference ($p < 0.5$) between those having a disabling or fatal stroke within the 3-year follow-up.

Patients having moderate stenosis showed an RR of stroke of 1.29 (95% CI, 0.88 to 1.9) for 30–49% stenosis and 1.18 (95% CI, 0.88 to 1.58) for 50–69% following CE. A higher proportion of strokes was disabling in the surgery group (42% versus 35%). The trial concluded that the risks of surgery outweigh any benefit and that surgery should only be performed within an RCT.

For patients with mild stenosis there was no statistically significant difference between the patients allocated to surgery and those to medical treatment, as regards the incidence of disabling or fatal strokes. The recommendation from the trial was that, due to risks associated with surgery there is no indication for CE in patients with less than 30% stenosis.

NASCET.[116] The benefit to patients with severe stenosis was a risk reduction of 17% (95% CI, 13.5 to 20.5) over 2 years for those patients allocated to surgery ($p < 0.001$). There was greater benefit with higher-grade stenosis: 26% (95% CI, 17.9 to 34.1) for patients with 90% to 99% stenosis; 18% (95% CI, 11.8 to 24.2) for 80% to 89%; and 12% (95% CI, 7.2 to 16.8) for 70% to 79% stenosis. The overall incidence of major stroke and death was 2.1% for the CE operation in this study.

Both studies show the benefits of surgery for patients with severe stenosis in the medium term (2–3 years) but the long-term benefits are not proven.

The benefit of surgery is dependent on there being a maximum of 2–3% mortality rate for the CE operation. If this rate is exceeded due to inexperience or other factors the benefit is not so clear cut and if the rate of major complication is more than 10% there is no benefit.

There was no benefit demonstrated following surgery for patients with mild stenosis.

Asymptomatic carotid stenosis

Four RCTs were identified.

- The European Carotid Surgery Trial (ECST)[117] randomised 2295 patients to surgical or medical treatment and followed-up the patients for a mean of 4.5 years.
- The Carotid Artery Stenosis with Asymptomatic Narrowing: Operation Versus Aspirin (CASANOVA)[118] trial randomised 410 patients with 50–90% stenosis to surgical or medical treatment.
- Hobson and co-workers[119] conducted a multicentre trial, with 444 men at Veterans Affairs medical centres randomised to medical treatment or medical treatment plus CE.
- Asymptomatic Carotid Atherosclerosis Study (ACAS)[120] randomised 1662 asymptomatic patients with 60% or greater stenosis to medical or CE.

ECST.[117] The degree of stenosis was found to be the most important predictor of stroke risk. The 3-year risk for the different categories of stenosis was: 0–29% occlusion: 1.8%, 95% CI, 1.1 to 2.6; 30–69%: 2.1%, 95% CI, 1.1 to 3.2; 70–99%: 5.7%, 95% CI, 1.5 to 9.8. This is a similar risk to that of stroke or death due to CE reported by the American Heart Association at about 3%. The 3-year risk of ipsilateral stroke was not significantly greater for medical than surgical treatment (5.7%, 95% CI, 1.5 to 9.8 versus 3.1%, 95% CI, 1.4 to 4.4). The authors concluded that there would be five strokes prevented in 127 patients with severe asymptomatic stenosis over 5 years. It was not, therefore, recommended to screen asymptomatic patients or treat by CE.

CASANOVA.[118] ITT analysis showed an odds ratio of 0.94 (95% CI, 0.57 to 1.98) for surgical versus medical treatment. For explanatory analysis the odds ratio was 0.88 (95% CI, 0.58 to 2.23). The authors' conclusion was that there is no statistically significant difference between surgical and medical treatment for asymptomatic carotid stenosis of between 50% and 90%. Mean length of follow-up was 3 years. Those with a stenosis of greater than 90% were excluded from the trial and had CE so no conclusions for this group can be drawn.

Hobson and co-workers.[119] The combined incidence of ipsilateral 'neurologic events' was 8% for surgical group and 20.6% for the medical group ($p < 0.001$). The incidence of stroke over the mean follow-up of 47.9 months was 4.7% (surgical) and 9.4% (medical). However, when the perioperative deaths and arteriography strokes were included, there was no statistically significant difference. The RR for all neurological events (surgical versus medical) was 0.51 (95% CI, 0.32 to 0.81). The authors conclude that CE, plus medical treatment, reduces the risk of overall incidence of neurological events (stroke and transient ischaemic attacks) in high-risk male patients.

ACAS.[120] This study followed patients for a mean of 2.7 years with estimation of events over a 5-year period. This showed an overall risk reduction (as proportion of risk in the medically treated group) for surgery of 0.53 (95% CI, 0.22 to 0.72), that is 53% reduction compared with medical treatment alone. There was only 20% reduction in the risk of any stroke (contralateral and ispsilateral) or death, with only a 5% absolute risk reduction. However, the benefit was greater for male patients 0.66 (95% CI, 0.36 to 0.82) but was not statistically significant for women 0.17 (95% CI, –0.96 to 0.65). The authors conclude that patients with asymptomatic stenosis of 60% or greater will have a reduced 5-year risk of ipsilateral stroke if CE is performed (assuming 3% perioperative morbidity).

Endovascular versus surgical techniques

A systematic review comparing endovascular with surgical CE was carried out according to the Cochrane Collaboration format in 1997.[121]

At that time there were no completed RCTs available but there is a trial due to be published soon – the CAVATAS trial[28] – which has randomised 550 patients. Therefore, no evidence is available to recommend endovascular treatment over surgical or medical treatment.

Appropriate rates of carotid surgery

Review of the literature illustrates marked differences in the overall rates of CE carried out in different countries, which may relate to differences in perception of the safety and efficacy of the procedure.[122] The overall rate for regions within the UK show that procedures for CE varied between 3.2 and 7.0 per 100,000 per year in 1994–95.[29] Studies from individual districts within the UK have shown rates of up to 9.0 per 100,000, while figures in Finland are around 12.0[56] and estimates from the USA may be several times this.[123] Most of these reported rates relate to periods prior to the publication of the large randomised trials referred to above and in most countries it seems likely that these studies will have expanded the indications for CE. There is evidence that in the USA about 20% of CEs may be carried out inappropriately,[124] though the problem in the UK is more likely to be under-provision.

Experience in Sheffield is that, with a neurologist assessing all carotid cases, there are a significant number of patients in whom CE is not carried out as it is felt to be inappropriate due to delays in identification and referral of these patients. This suggests that even at the highest rate within North Trent (approximately 8.0 per 100,000 per year) the current rate of CEs does not include all patients that could benefit from the procedure and may therefore be subject to increase over the next few years.

Summary

The results of the large RCTs of CE show that in symptomatic patients, with the appropriate indications, surgical treatment will save approximately one stroke over the subsequent 3 years for every six patients treated by CE. These benefits depend upon there being a low rate of surgical complications. In the case of asymptomatic patients, although some of the trials have shown a small benefit there is still considerable debate about the place for CE.

The current practice in North Trent is only to treat symptomatic patients. In comparison with figures from other sources it seems likely that even in the districts with higher rates of CE, there are a significant number of symptomatic patients who remain untreated due to lack of awareness and delays in referral.

Rates of reconstruction and amputation

Local data

As stated above, one of the difficulties with PVD is that the current coding systems do not allow adequate separation of casemix, as regards the distinctions between patients with intermittent claudication, chronic critical ischaemia and acute ischaemia. It is thus difficult to draw any conclusion as regards outcome from using mortality data. The crude data show considerable variation with mortality following vascular reconstruction, varying between 2.1% and 7.1% following elective admission and between 5.4% and 27.3% following emergency admission. Although figures at the higher end of these ranges are clearly of concern, there is not sufficient information about casemix to analyse these in further detail.

As regards the use of amputation as an outcome indicator, it is difficult to draw conclusions from the number of procedures performed at particular units due to the difficulty with interpreting the selection that takes place in cross-boundary flows. Thus, a higher proportion of amputations compared with reconstructions may simply represent the fact that patients who are suitable for reconstruction are selectively referred to another centre. It may, however, be possible to draw some conclusions from overall amputation rates within a particular district. Previously published results have shown an inverse relationship between the number of reconstructions that are carried out and the population-based rates of new amputations.[66] If such a trend exists one would expect that it would be most marked in comparing emergency reconstructions or femoro-distal bypass, many of which are carried out for limb salvage, with the rate of amputations. Comparison between rates for Sheffield and the other non-Trent districts would appear to support the published findings. Patients who live in the Sheffield district are nearly three times more likely to undergo a femoro-distal bypass and 72% more likely to undergo an urgent vascular reconstruction, whereas patients in the rest of North Trent have a 46% higher rate of major amputation (see *Figure 3*).

In addition to the overall rate of amputation, the level of amputation has been suggested as a possible outcome indicator.[125] Over the Trent region the proportion of amputations carried out below the knee, averages 45% (range, 12.6–65.3%) the proportion in

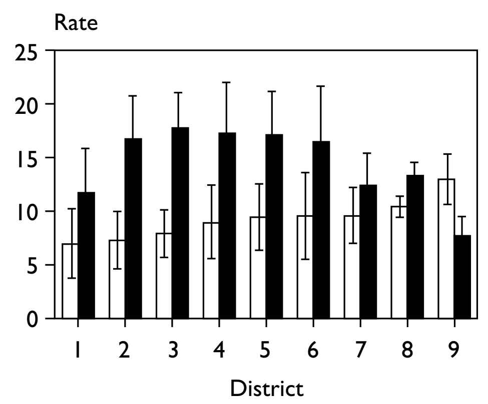

FIGURE 3 *Rates of admissions (per 100,000 population per year) for patients undergoing femoro-distal reconstruction or other vascular reconstruction following emergency admission for all districts within Trent. Districts are in ascending order of total rates of combined reconstructions. Error bars represent 95% CIs (□, reconstruction; ■, amputation)*

Sheffield being 53.5% (95% CI, 45.6 to 61.4%) compared with 29.3% (95% CI, 22.8% to 25.8%) for the rest of North Trent.

Published data

The outcome data reported above appear to show an inverse relationship between the rates of reconstructive surgery and amputation. As many of the procedures, particularly emergency and distal grafts, are carried out for limb salvage in patients with critical ischaemia, such an association would seem reasonable. The literature has been reviewed to look for evidence that such an association exists.

Because of the nature of the problem it is not an area in which there are RCTs. However there are two kinds of study reported in the literature that may give some indication of the presence of such an association and, if so, an estimate of the magnitude of the effect. The first of these are longitudinal studies, which show trends in the use of various procedures over a time period for a given population. The second are cross-sectional studies, which compare the practice in different areas and the rates for procedures of different sorts within these areas. Both of these studies suffer from some problems in accounting for the other factors that may influence rates of procedures or amputation.

- In longitudinal studies there have often been changes in the population (e.g. age-mix) and may be trends in the incidence of particular diseases.
- There may also be trends in management other than simply the change in rates of use of particular procedures.
- Cross-sectional studies may show differences due to casemix differences between different districts.
- There may be contamination by cross-boundary flows.
- It is frequently difficult to distinguish procedures carried out for intermittent claudication and those carried out for critical ischaemia, and the former would not be expected to significantly alter amputation rates.
- Amputation rates may be altered by differences in the management of elderly patients with ischaemic legs. It has previously been suggested that many amputations are carried out inappropriately in elderly people.

These factors should be taken into account in considering the published literature.

The issue of correcting the casemix in considering bypass surgery was considered by Elfstrom and co-workers[126] who demonstrated a number of factors that differed between different hospitals and that were related to mortality and amputation rates. These included patient factors (e.g. age, diabetes and heart disease), procedural factors (e.g. the site of the distal anastomosis and graft type), and also the hospital where the procedure was carried out.

The results of a nationwide survey in Finland showed similar differences in casemix that were clearly associated with amputation rates.[57] These factors included surgeon's annual caseload of less than ten procedures and hospital volume of fewer than 20 procedures. In a study of the factors affecting the mix of procedures in Baltimore it was found that the rates of particular procedures varied not only with patient factors, such as diabetes, age and hypertension, but also with race and insurance status.[127]

In can thus be seen that there is difficulty in interpreting such data. However, there are a number of papers that have attempted to consider the problem.

A frequently quoted paper from Maryland[128] showed that over the years between 1979 and 1989 there was a very large increase in the rate of angioplasty and bypass surgery, with no change in the overall rate of amputation. This paper has been cited as evidence that vascular surgery does not influence amputation rate. However, there are a number of issues regarding this paper that throw its results into question. In particular there is no correction for casemix and the high rate of procedures make it likely that a relatively small proportion of them were carried out for critical ischaemia.

Another study that looked at the impact of percutaneous transluminal angioplasty (PTA) on surgical operation rates and amputation found a large increase in the use of PTA in association with an increased rate of reconstructive surgery.[129] There was also a more moderate increase in the rate of amputation, which levelled off after the first part of the study. It is notable that the increase in the rate of reconstruction was not seen among patients with critical ischaemia.

The rate of femoro-distal bypass and lower limb amputation in Queensland, Australia were found to have an inverse relationship.[130] The decrease in the rate of amputation was associated with an increase in the number of bypasses to the infra-popliteal arteries.

In a study in Sweden a strong inverse relationship was reported between the rates of vascular interventions for limb-threatening ischaemia and the rates of amputation, with a 65% increase in the reconstructions being associated with a rate of amputation that was less than half.[131]

In Western Australia there was found to be a decreasing trend in major amputations without an overall rise in surgery.[132] However there were changes in the sort of procedures being carried out and a reduction in non-amputation vascular surgery was seen in younger patients.

In a study of a single district in Finland, a 100% increase in surgery for critical limb ischaemia was found to be associated with a reduction in an amputation rate of 60% over the same period.[133]

A Swedish study of cross-sectional design looked at variation in local rates for vascular reconstruction and amputation in western Sweden.[134] This failed to demonstrate any negative correlation between the two; however, they noted considerable differences in the demographics of patients undergoing amputation and revascularisation, suggesting that the reconstruction was not being carried out on the patients at risk of amputation.

A study from the Oxford region in the UK showed an inverse relationship between the rates of amputation and the overall provision of vascular reconstruction between differing neighbouring districts.[66] This also demonstrated that districts with a higher rate of vascular reconstruction carried out a greater proportion of more distal major amputation.

An association between increased rates of vascular reconstruction and the proportion of more distal amputations has also been demonstrated elsewhere.[135]

Summary

Although there are considerable difficulties in interpreting these data due to problems in correction for casemix and time trends, it would appear that those papers that concentrate upon vascular surgery for critical limb ischaemia or upon femoro-distal bypasses demonstrate the presence of an inverse relationship to amputation rates. These findings are based on a limited review of the literature and a full systematic review would be beneficial in clarifying the existing evidence. These findings are, however, in keeping with the local data, which suggest that lower rates of vascular reconstruction may be associated with an increase of approximately 50% in the rate of major amputation and in the proportion of more distal amputations.

Use of angioplasty

As described in chapter 3 (*Admission rates*), there is considerable difference in the rates of angioplasty at different provider units, with some units recording very few angioplasties. It is difficult to relate this to any measures of outcome from the local data. Although theoretically the mortality and amputation rate may indicate the outcome, there are very great differences in casemix and the type of procedures that are undertaken, which make such comparisons meaningless. There are also known to be very considerable differences in the use of intra-arterial stents, which is mainly confined to the teaching hospital.

As described in the section on reconstruction and amputation above, there has been a considerable increase in the use of angioplasty in recent years.[128,129] However, this does not appear to be associated with a significant decline in the number of vascular reconstructions or amputations. This is not a surprising finding, as the literature on the use of angioplasty reports that the majority of centres use it primarily for the treatment of claudicants and its use for critical ischaemia is variable.[136] There are increasing reports of the use of angioplasty and stenting in patients with more severe ischaemia, either as a solitary procedure or as an adjunct to vascular reconstruction.[137]

In order to consider the value of angioplasty in differing clinical situations a decision model has been constructed. The probabilities required for this exercise have been obtained by a review of the literature and this is described in greater detail below, along with the derivation of utility values and results of the model (see chapter 5, *Decision analysis*).

Material for femoro-popliteal bypass

Local data

As has been described, there is considerable variation in the proportion of femoro-popliteal bypasses that are carried out with prosthesis rather than vein graft within Trent. The main

TABLE 26 Estimated 5-year patency of prosthetic bypass and autologous vein for femoro-popliteal bypass[138]

	Above knee	Below knee
Prosthetic material	43.2%	26.6%
Autologous vein	61.8%	68.4%

expected differences between these materials are in the long-term patency, and the current data do not allow this to be analysed.

In the future any performance indicators that are used to examine the overall rates of reconstructive procedures for PVD will rely upon the linking of records in order to ascertain long-term figures for patency, re-operative procedures and late amputations. Without such data there is clearly a risk that the emphasis on short-term outcomes, such as early amputation and mortality, will produce a bias towards simpler procedures that have inferior long-term results.

Published data

A full systematic review of the issue of graft material for femoro-popliteal bypass surgery has recently been carried out by the Cochrane Collaboration.[31] Only a single, high-quality, RCT was identified which compared autologous vein with prosthetic material. This suggested that the primary patency at 4 years was 73% for vein compared with 47% for polytetrafluoroethylene and 54% for Dacron.

Although, taken alone, this is fairly limited evidence, it is in keeping with an analysis of other trials that suggest an advantage for vein of about 20% in the first year and 5% per year following this with a greater advantage below the knee (*Table 26*).[138] The apparent failure of some studies to demonstrate this difference in above-knee femoro-popliteal bypasses may relate to the fact that the trials were small and the overall occlusion rates were lower, making a Type II error more likely.

Summary

The practical effect of the difference in use of materials on outcomes is difficult to predict, as it is impossible to determine the indications for particular grafts from the local data. This is important in predicting the effects on outcome as there is a tendency, in line with some published papers, to prefer the use of synthetic grafts for above-knee femoro-popliteal bypasses for intermittent claudication. In this situation there is considerable doubt about the cost-effectiveness of arterial reconstruction and some evidence that failure of a prosthetic graft may carry increased risk of limb loss.[139] Angioplasty or conservative management may be better treatment for such patients (see chapter 5, *Decision analysis*).

On the other hand, centres with an aggressive policy on the use of autologous vein for bypass surgery may attempt to use prosthetic materials only as a last resort for re-operative surgery, when there is no available autologous vein. In these circumstances the realistic alternatives are prosthetic graft and amputation and the outcome issues are therefore very different. Some of these issues have been addressed in relation to the modelling of outcomes (chapter 7, *Implications for outcomes and cost*).

Summary of outcome issues

Overall, the consideration of the effect of reconfiguration of services upon outcomes suggests that the following issues need to be considered in assessing the possible impact of such changes.

- Altered mortality following aortic surgery due to the relationship with volume of procedures carried out by individual practitioners and/or centres.
- Changes in the rates and levels of major amputation.
- Differences in outcomes for patients with PVD due to differences in the use of angioplasty.
- Differences in graft patency due to the use of prosthetic grafts.
- Differences in stroke rates due to variation in the rates of CE.

Chapter 5
Patient preferences

In determining the effect of the configuration of services on outcome, an important aspect is consideration of patient preferences. These have been incorporated in the analysis in two ways.

In the case of the treatment of PVD, there are a number of potentially different outcomes, such as amputation, symptomatic vascular disease, and mortality. In order to assess the relative merits of configurations that provide differences in these outcomes, it is necessary to evaluate the comparative strength of preference for the alternative outcomes of any particular treatment.

A study has been carried out to identify the patient utilities attached to such outcomes using a standard gamble technique. The data obtained have been used in a decision model in order to address the specific issue of the value of angioplasty for treating patients with symptoms of PVD.

Another issue that arises is the preferences that patients may have for some aspects of their care, which are not directly related to clinical outcome. For example, quality of hotel services, waiting times, and location of services may be important to patients and they may be prepared to trade differences in clinical outcome against these other aspects of the service. This issue has been addressed through the use of a technique known as conjoint analysis.

There are issues surrounding the choice of sample for the determination of patient preferences. The standard gamble valuation exercise was undertaken in order in order to estimate quality-adjusted life years (QALYs) for different treatment options in the decision analysis. The convention of using the views of the general population for informing resource allocation decisions has been adopted. However, the conjoint analysis was more concerned with the views of vascular patients about alternative models of care. As these patients may differ from the general population a sample of patients with PVD has been used in this exercise.

Decision analysis

The place of angioplasty

One of the difficulties in predicting the effect upon outcomes of any changes in the configuration of services is that there are a number of possible outcomes with qualitative differences. For example, in the case of PVD different treatment of claudicants or patients with critical ischaemia may result in an alteration of the mortality, the number or level of amputation or the proportion of patients who are left with symptoms of claudication or critical ischaemia.

The workload data suggest that there is considerable variability in the use of angioplasty and the effect that this may have on outcomes is not clear. In order to compare such qualitatively different outcomes an attempt was made to assign utilities to each of these outcomes in order that decision analysis can estimate the expected QALYs resulting from different treatment options.

Decision analysis is a way of formalising decisions to explore the options available and help select appropriate treatments. Complex decisions can be broken down into more manageable segments.[140] It also allows decisions to be explored where there is incomplete information or uncertainty[125] as is often the case in claudication and critical limb ischaemia.

Probabilities of the various treatment outcomes for the different decision pathways have to be calculated from the best available evidence.[141] In addition, valuation for outcomes for the various treatment options have also to be included within the model. These are often applied in the form of QALYs, which are the product of utility and life expectancy estimates. One of the most established methods of estimating utilities[142] for health states is the standard gamble method as this has a basis within decision theory.[143] The expected outcomes (expected QALYs) for each of the pathways are calculated and that with the highest expected outcome score should be the treatment of choice.

Standard gamble

The standard gamble is a method of obtaining utility values for health states. These values can be used to calculate QALYs or included in decision analysis. Standard gamble is based on a respondent making a choice between two alternatives: one of which is certain, while the other is uncertain.

The uncertain outcome (Choice 1) consists of two possible options: full health and immediate death. The certain outcome (Choice 2) has only one outcome h_i (the health state), which will last for the rest of the subject's life. The probability (p) of full health is varied until the subject is 'indifferent' between the two alternatives being offered. Where full health is valued as 1 and death is set to 0, then the utility of h_i is equal to p.[144]

The implication of the interviewee's choice is that the 'worse' a chronic health state is perceived by the subject then the more risk they will be willing to take to avoid ending up in that health state, that is the lower the value of p.[145]

For states worse than death the choices are modified slightly. There are still two possible outcomes but now the certain choice (Choice 2) is immediate death. The uncertain choice (Choice 1) is now a choice between the health state and full health: again the probability (p) is varied to the point of indifference.

For states rated worse than death the utility is calculated by:

$$U = \frac{-p}{(1 - p)}$$

The standard gamble method for obtaining utilities has been described by its adherents as the gold standard[142] and the classical method for measuring cardinal preferences.[146,147] Standard gamble is held in high regard by health economists, and others, because it is based on the von Neuman–Morgenstern theory, which describes decision making under conditions of uncertainty.[143] This model purports to be a model of how people should behave when faced with uncertain outcomes.

The use of the standard gamble technique is advocated in medical decisions, particularly those including surgical options, as it implicitly models the context within which patients make a decision when confronted by the clinical situation. The decision regarding treatment and the standard gamble model both include the element of uncertainty. The patient has to weigh uncertain outcomes and decide on which alternative they prefer.[148]

A possible criticism of the standard gamble methodology is that patients often have difficulty in understanding the concepts of probability,[149] and so the validity of the utility scores obtained may not be reflections of a persons true preference. In addition, it can be labour intensive, difficult to administer and involve a lot of resources in terms of equipment and training.[149]

Health economists such as Torrance and Feeny defend the use of standard gamble in preference to other techniques, such as time trade-off and visual analogue scales, as standard gamble has a more rigorous theoretical foundation.[144,147] Standard gamble is not perfect but it is thought by many to be the best technique that is currently available for valuing health states for the purpose of conducting decision analysis.

Methods

Literature search for probability and life expectancy data

Searches for articles concerned with intermittent claudication and critical limb ischaemia were performed on the MEDLINE, EMBASE, CINAHL and the Cochrane Library databases. The aim was to identify RCTs or meta-analyses or systematic reviews to provide information regarding probabilities for use in the decision tree. Where there was no Type 1 evidence (defined by the CRD as well-designed RCTs[150]) available retrospective, non-controlled studies were included.

Decision tree construction

Decision trees for the treatment of acute limb ischaemia and intermittent claudication were constructed on the basis of published literature and in consultation with vascular surgeons at the NGH. Key health states were identified and placed within the decision tree at the appropriate points. The number of health states was restricted to six as it was felt that the interviewee's would not be able to value more than this in one sitting, resulting in a compromise on the complexity of the decision tree. The restricted number of health states meant that they had to be generic rather than specific.

The constructed decision trees for acute limb ischaemia and claudication are shown in *Figures 4* to *6*.

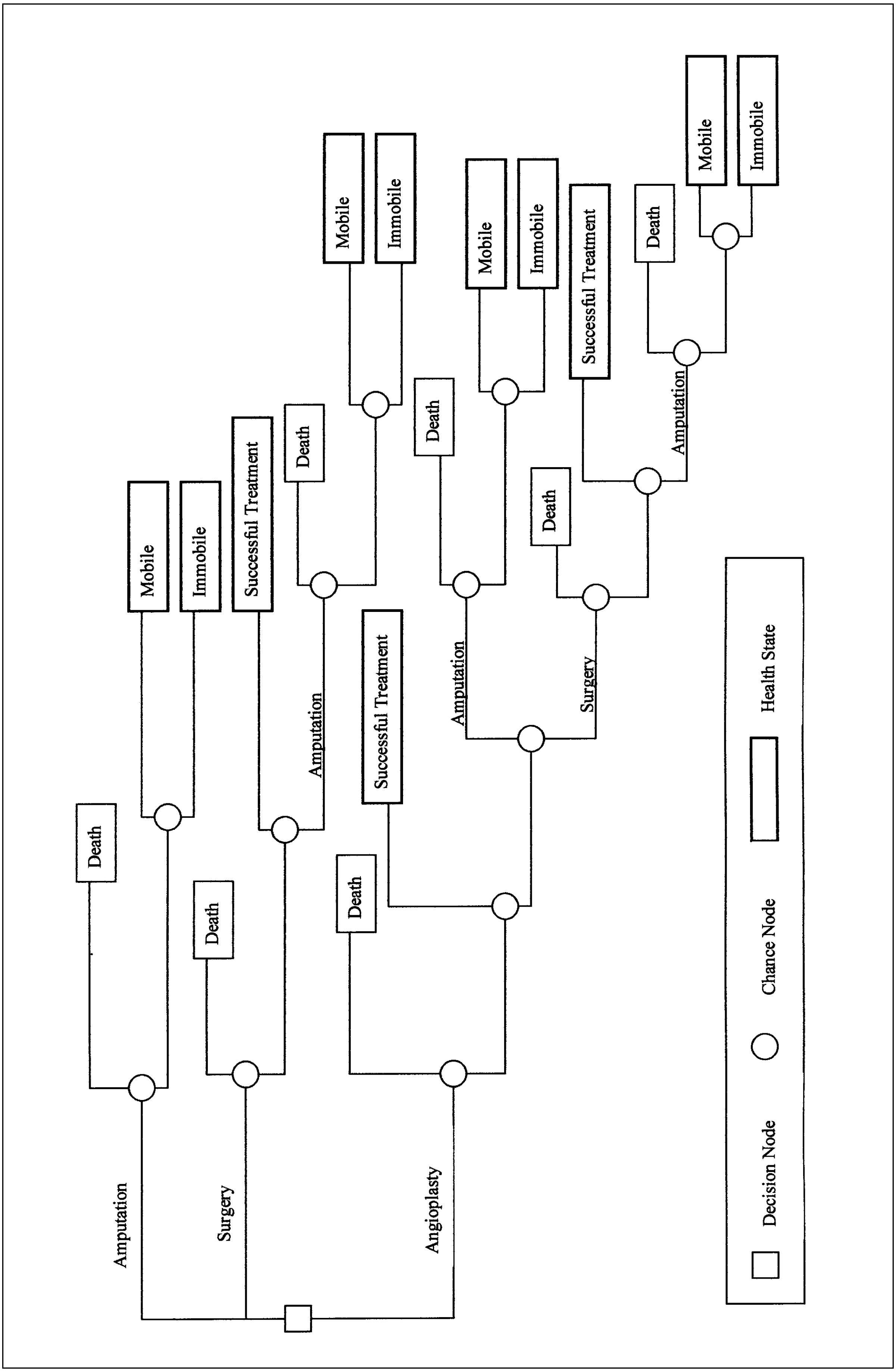

FIGURE 4 *Decision tree for critical limb ischaemia treatment options*

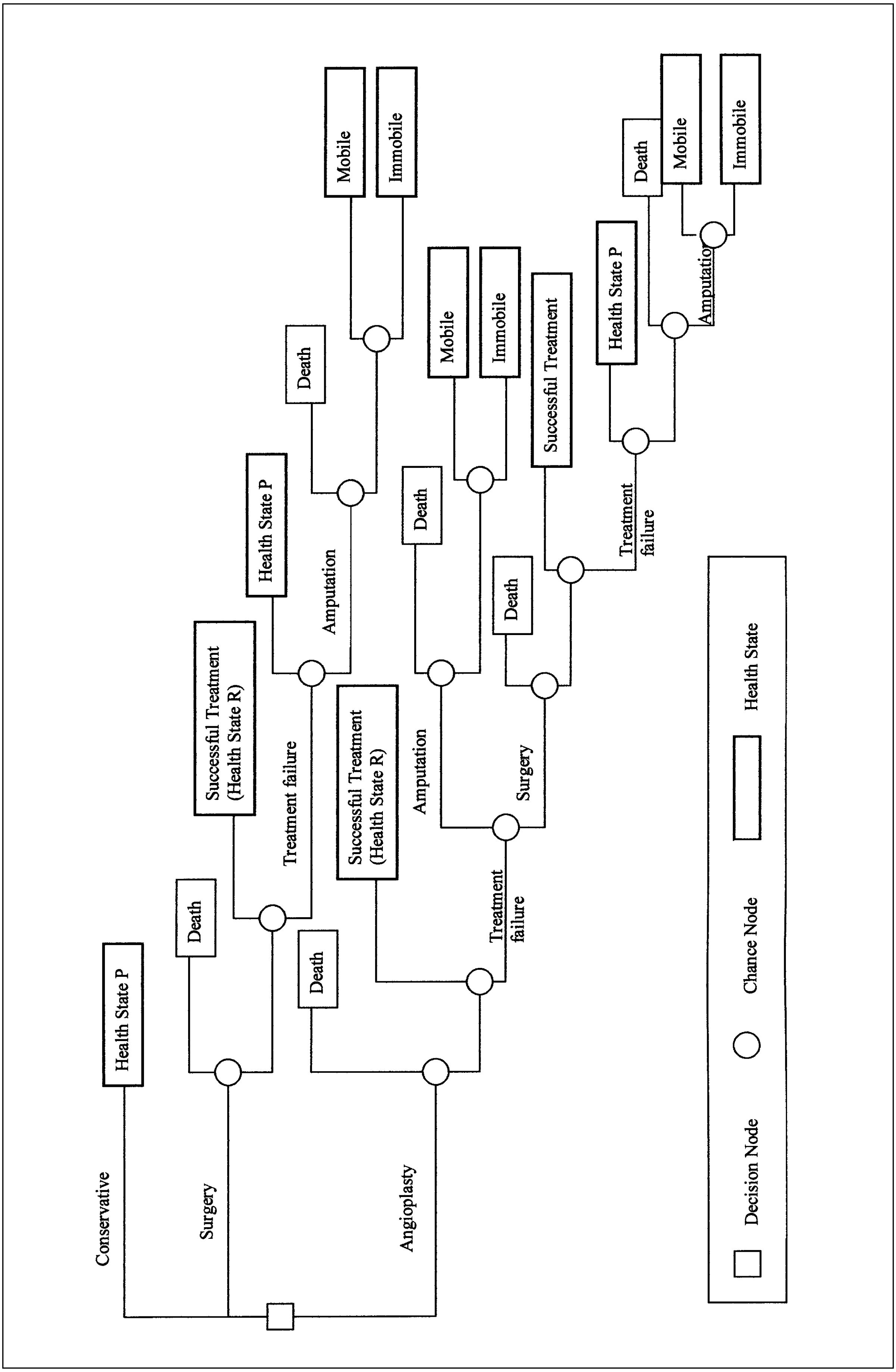

FIGURE 5 *Decision tree for short-distance claudication treatment options*

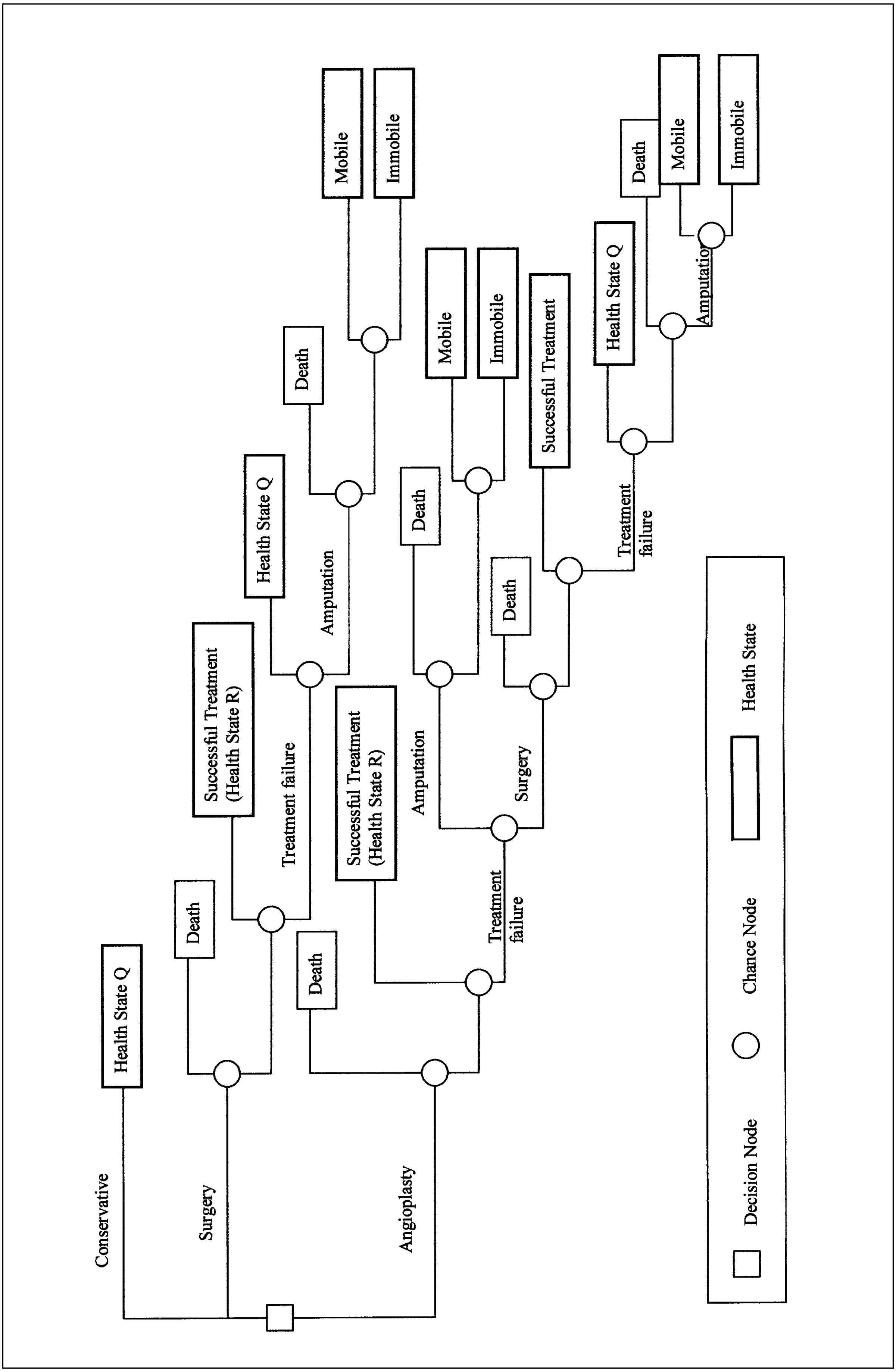

***FIGURE 6** Decision tree for long-distance claudication treatment options*

Health state construction

The health states for the decision trees were constructed in collaboration with two vascular surgeons, a consultant radiologist, a vascular nurse specialist and a consultant physician in rehabilitation medicine. Their opinions were sought on the characteristics of patients with intermittent claudication and critical limb ischaemia. They were asked to describe the likely presentation of a 'typical' patient in terms of mobility, pain, self-care, emotional state and activities. Aggregate health state descriptions were constructed from this information and feedback obtained from the experts until consensus was obtained. The health states that resulted from this process are shown in *Box 1*. The health states contain various dimensions describing mobility, personal hygiene, usual activities, pain and anxiety/depression.

Health state valuation survey

A pre-pilot of the questionnaire was carried out on a convenience sample at the NGH, followed by a pilot study of ten members of the general public. The pilot studies were used to modify the questionnaire and interview schedule, resulting in a simplification of the language used and a shortening of the interview schedule.

For the main study, 100 people from the general population were recruited in four districts of Sheffield: Dore, Nether Edge, Darnall and Netherthorpe using a convenience sample obtained through approaching houses within a random selection of streets in the selected districts. Members of the general public were chosen as it was hoped to obtain societal valuation for the health states as it would be the wider society that would have to pay for any organisational changes.

The sample size for the study was based on tables produced by Furlong and co-workers,[151] which indicated that a sample size of between 100 and 110 would have sufficient power to detect a mean difference of 0.06 in utility values for health states. This was considered sufficiently accurate for the purpose of this study based on the time and resources available.

Standard gamble questionnaire

A copy of the full questionnaire and interview schedule can be found in appendix 4.

The questionnaire was divided into three sections.

- The first section included questions on the background characteristics of the participants and included the EuroQol health questionnaire.[152]
- The second section involved a ranking exercise of the health states.
- The third section involved the participant valuing the health states using the standard gamble method.

The ranking exercise involved the participant in ranking a total of eight health states – the six used in the decision tree, plus immediate death and full health (health state S). The participant was asked to place the health states in their preferred order from best to worst.

A no-props variant of the standard gamble technique was chosen to obtain utility valuations. This varies from the more traditional method, as described by Torrance,[146] in that there is no chance board or props. Instead the interviewee is presented with a probability table illustrating the chance of success and failure from 100% to 0%. They are then asked to mark on the table the probabilities where they are confident that they would: take the risky treatment (by placing a tick), reject the treatment and accept to stay in the health state described (by placing a cross), and where it would be difficult to choose (by placing an equals). The standard gamble options presented to the participants are shown in *Table 27*.

The utility score for the health state was equivalent to the point of indifference marked on the probability table (i.e. the equals). Where the interviewee had not placed an equals, but had only placed ticks and crosses, the utility was taken to be the midpoint between the lowest tick and the highest cross. Where 100% chance of success was ticked and the 95% crossed the utility was deemed to be 0.975. The validity of assuming the midpoint as being equivalent to the utility was tested by sensitivity analysis.

There was no evidence identified showing that any of the other available methods (including computer-assisted evaluation) were superior, and so on pragmatic basis the no-props method was chosen. It was felt that the no-props method had several advantages.

- It would be easier for interviewers to learn.
- It would cheaper to administer as there is no need to make or purchase chance boards and other equipment.
- It would take less time as the interviewer explains the concept, ensures understanding,

BOX 1 **Health states used for the standard gamble exercise**

Health state L • You will be confined to bed • You will be dependant on the nursing staff for help with **using the toilet, dressing and washing** • You will be unable to carry out any of **your usual activities** • You will be experiencing very severe **pain** in the affected limb, which will need morphine to control • You will feel extremely **anxious, depressed and frightened**	Health state M • You will be able to **walk** a distance of less than a quarter of a mile with the use of an artificial leg • You will need occasional assistance with **washing and dressing** • You will have some problems with performing your **usual activities** • You will experience '**phantom**' **pain** in the leg that has been amputated, which will cause you some discomfort • You will feel **anxious and depressed** for some of the time
Health state N • You will be confined to a **wheelchair** • You will need assistance with **washing and dressing** • You will have a lot of problems performing **your usual activities** • You will be experiencing '**phantom**' **pain** in the leg that has been amputated, which will cause you some discomfort • You will feel **depressed and anxious** most of the time	Health state P • You are likely to be limited to **walking** short distances (less than 50 yards) before having to stop due to cramp-like pain in your legs. After 5 minutes the pain will have stopped and you will be able to carry on walking • You will need occasional assistance with **washing and dressing** • You will have some problems with performing your **usual activities** • You will have **cramp-like pain** in your legs at night, which will wake you up • You are likely to feel **anxious and depressed** some of the time
Health state Q • You will be able to walk up to a quarter of a mile before having to stop due to cramp-like pain in your legs. After 5 minutes the pain will have stopped and you will be able to carry on walking. • You will be able to **wash and dress** yourself without any help • You will have some problems performing your **usual activities** • You will not feel **anxious or depressed**	Health state R • You will be able to **walk** up to a quarter of a mile before you will have to stop and rest due to cramp-like pain in your legs. After 5 minutes the pain will have stopped and you will be able to carry on walking • You will be able to **wash and dress** yourself without any help • You will have some problems performing your **usual activities** • You are likely to have mild wound **pain** in your leg for which you will need to take paracetamol • You will feel **anxious and depressed** some of the time
Health state S (full health) • You will have no problems with **walking** • You will have no problems with **washing and dressing** • You will be able to do your **normal activities** • You will have no **pain or discomfort** • You will not feel **anxious or depressed**	**Immediate death**

TABLE 27 *Standard gamble options presented to study participants*

Health state – for certain	If 'treatment' works	If 'treatment' does not work
L – acute limb ischaemia no active treatment	Full health	Death
M – mobile amputee	Full health	Death
N – immobile amputee	Full health	Death
P – short-distance claudicant	Full health	Death
Q – long-distance claudicant	Full health	Death
R – post-treatment for claudication	Full health	Death
For states valued worse than death		
Immediate death	Full health	State valued worse than death

and the interviewee completes the questionnaire at their own speed.

Data analysis

This was carried out using the Statistical Package for the Social Sciences, Access, Excel, and Data 3.0 software programs. Differences between means of continuous variables were tested using *t*-tests and differences between proportions by the chi-squared test. The justification for using health state utility means as the best estimate has been based on them having interval-scaling properties.[151] However, box plots were performed and where there was significant skewing of results non-parametric tests were used to test differences.

Results

The background characteristics of the sample are shown in *Table 28*.

A total of 110 interviews were completed in the participants' own homes, requiring contact to be made with 160 people. A total of 49 people refused to participate in the survey, and one person was excluded due to not speaking English, giving a response rate of 68.75%.

Description of sample

The ages of the participants ranged from 16 years to 85 years, with a mean age of 46 years and a median age of 40.5 years. Approximately 24% of the sample were aged 65 years and over. Fifty-two (47.3%) were male and 58 (52.7%) were female. Fifty-one per cent had been educated until at least 18 years old. A large proportion (52.8%) of the sample were either retired or unemployed, which could have been a reflection of the survey method used and the times that recruitment took place. The only significant differences between the sample and the general populations related to educational attainment and employment.

Self-reported health was determined from the EuroQol questionnaire using an algorithm described by Dolan,[153] which allows the calculation of EuroQol scores based on the scores for the various dimensions – with the value of 1 equal to full health. The mean score for the sample was 0.87 (standard deviation (SD), 0.2). The majority of the sample (71%) were in full health.

The sample was not intended to be representative of the general population of the UK but demographic details were compared. The study differed from the UK general population in terms of education ($p < 0.001$), occupation ($p < 0.05$) and employment ($p < 0.05$) but was well matched on age ($p = 0.96$) and gender ($p = 0.37$).

The probable reasons for the differences were the method used to obtain the study sample, and the times when the interviews took place, with over 70% of the interviews being between midday and 5 pm. This time frame would mean that the majority of the working public would not be at home and so the people available for interview would tend to be the unemployed, students or the retired.

Comprehension

The questionnaire was perceived as being 'difficult' to comprehend by 46.4% of the interviewees but only 6% found it 'very difficult'. The interviewer-assessed comprehension confirmed the difficulty some respondents were having with the task, 42% of the participants 'having some difficulty' but only 9% gave the impression that they had not understood the task (*Tables 29* and *30*).

TABLE 28 *Demographic information*

	n **(%)**
Age (years)	
Mean (SD)	46 (20.5)
Median	40.5
Minimum	16.0
Maximum	85.0
Age range (years)	
16–34	38 (34.5)
35–54	34 (30.9)
55–64	12 (10.9)
65–74	12 (10.9)
75+	14 (12.7)
EuroQol score (self-reported health)	
Mean	0.874
SD	0.215
Median	1.0
25th percentile	0.76
75th percentile	1.0
Sex	
Male	52 (47.3)
Female	58 (52.7)
Location	
Darnall	25 (22.7)
Dore	25 (22.7)
Nether Edge	25 (22.7)
Netherthorpe	35 (31.8)
Education	
To 16 years	48 (49.0)
To 18 years	9 (9.2)
Post 18 years	41 (41.8)
Employment	
White collar	32 (29.1)
Blue collar	6 (5.5)
Student	11 (10.0)
Retired	28 (25.5)
Unemployed	30 (27.3)
Own health	
Full health	71 (64.5)
Less than full health	39 (35.5)

Note: Definition of employment – white collar, non-manual occupation; blue collar, manual occupation; unemployed, looking for work, unable to work or looking after the home

TABLE 29 *Self-assessed comprehension*

	n **(%)**
Very difficult	7 (6.4)
Quite difficult	44 (40.0)
Neither difficult or easy	36 (32.7)
Fairly easy	17 (15.5)
Very easy	4 (3.6)
Missing	2 (1.8)

TABLE 30 *Interviewer-assessed comprehension*

	n **(%)**
Understood the task without difficulty	49 (44.5)
Some problems, but understood the task in the end	46 (41.8)
Doubtful that respondent understood the task	10 (9.1)
Missing	2 (4.5)

The interviewer assessed comprehension of the respondents tended to be associated with age ($p < 0.001$). The mean age of the group that the interviewer assessed as 'doubtful understood the test' was 74.1 (median age, 75.5 years).

Excluded respondents

The decision on which participants should be excluded from the analysis, or as it is euphemistically called 'cleaning' of data, is an issue that can be controversial. The exclusion of participants deemed to be 'confused' would tend to increase the precision of the health state utility values. However, as the sample size decreases the representiveness of the sample also decreases. There could also be an additional problem of assessment bias occurring as the researcher may exclude participants because they do not fit the model they perceive to be the correct one.

The decision in this study was to only exclude respondents who had not valued all six of the health states, rather than apparent comprehension problems. This was in order to avoid variations in health state utility values arising from differences in the sample. Five respondents were excluded from the analysis as they did not value all six health states. Sensitivity analysis was carried out to examine if there was any effect on the utility scores. Sensitivity analysis was also performed on those respondents who appeared to be confused (i.e. those who had reversed the implicit rank of the health states), and those who refused to take any risk and valued all the health states as equal.

Ranking exercise

The results of the ranking exercise are shown in *Table 31*. The best health state is ranked as 1 and the worst is ranked as 8.

The worst health state was 'death' with 81.8% ranking this as eighth (out of 8). The worst of the six core health states was health state L (describing a bedbound acute limb ischaemic) with 60% ranking this as seventh. The best health state was 'full health' (health state S) with 98.2% ranking this first, and the best of the core health states was health state Q with 60% ranking this as second. There appeared to be less of a consensus with the health states ranked fourth (health state P) and fifth (health state M), with 37.3% and 39.1%, respectively.

The majority of the participants ranked the health states in an order consistent with the implicit rank of the logically consistent order. There were those who ranked health states L ($n = 18$) and N ($n = 6$) as worse than death, which could be a reasonable reaction. However, there were two respondents who ranked health states P and Q as worse than death, which could indicate that they had not understood the exercise. In addition, they both rated the health states as better than death in the standard gamble exercise. Both these participants were elderly (aged 67 and 80 years, respectively), and the interviewer rating of their comprehension of the questionnaire was doubtful that they understood the exercise.

Standard gamble values

The descriptive statistics of the health state standard gamble values are shown in *Table 32*. The utility scores are anchored between 1.00 for perfect health and 0.00 for death, scores with a negative value mean that the health state was rated as being worse than death.

The standard gamble values were found to be non-normally distributed and so non-parametric tests would generally be indicated. However, within economics there are accepted reasons for using mean values,[154] as this measures the strength of preference, rather than the median which is a measure of central tendency. Most of the published studies have used *t*-tests and mean values when making comparisons between utility values,[155–157] and this policy was adopted in the current study.

The differences between the utility values for the health states were found to be statistically significant ($p < 0.001$) using both the paired *t*-test and the non-parametric Wilcoxon test for matched

TABLE 31 *Ranking exercise: rank of health states*

	Health state							
	L *n* (%)	M *n* (%)	N *n* (%)	P *n* (%)	Q *n* (%)	R *n* (%)	S *n* (%)	Death *n* (%)
1	1 (0.9)	0 (0)	0 (0)	1 (0.9)	1 (0.9)	0 (0)	108 (98.2)	0 (0)
2	1 (0.9)	6 (5.5)	1 (0.9)	9 (8.2)	77 (70)	16 (14.5)	0 (0)	1 (0.9)
3	0 (0)	7 (6.4)	2 (1.8)	18 (16.4)	20 (18.2)	61 (55.5)	0 (0)	1 (0.9)
4	0 (0)	27 (24.5)	3 (2.7)	41 (37.3)	7 (6.4)	30 (27.3)	1 (0.9)	2 (1.8)
5	11 (10)	43 (39.1)	16 (14.5)	32 (29.1)	3 (2.7)	2 (1.8)	1 (0.9)	1 (0.9)
6	13 (11.8)	20 (18.2)	66 (60)	7 (6.4)	0 (0)	1 (0.9)	0 (0)	2 (1.8)
7	66 (60)	7 (6.4)	22 (20)	1 (0.9)	1 (0.9)	0 (0)	0 (0)	12 (10.9)
8	18 (16.4)	0 (0)	0 (0)	1 (0.9)	1 (0.9)	0 (0)	0 (0)	90 (81.8)
Median rank	7	5	6	4	2	3	1	8
25th percentile	7.0	4.0	6.0	3.0	3.0	3.0	1.0	8.0
75th percentile	7.0	5.25	6.0	5.0	5.0	4.0	1.0	8.0
Mean	6.75	4.78	5.9	4.1	2.5	3.2	1.06	7.6
SD	1.09	1.2	0.873	1.16	1.0	0.74	0.46	1.0

$p > 0.001$ *for differences between the rankings using the Wilcoxon test for two related samples*

***TABLE 32** Health state: mean (95% CI), median, percentiles and ranges of utility values*

	Health state					
	L ***n* (%)**	**M** ***n* (%)**	**N** ***n* (%)**	**P** ***n* (%)**	**Q** ***n* (%)**	**R** ***n* (%)**
Mean	0.325 (0.26 to 0.39)	0.56 (0.52 to 0.6)	0.45 (0.41 to 0.5)	0.70 (0.66 to 0.73)	0.79 (0.76 to 0.82)	0.79 (0.76 to 0.82)
SD	0.34	0.20	0.21	0.18	0.15	0.16
Median	0.45	0.50	0.50	0.75	0.80	0.85
25th percentile	0.20	0.45	0.38	0.60	0.75	0.73
75th percentile	0.50	0.70	0.55	0.80	0.88	0.90
Minimum	–1.34	0.05	–0.54	0.05	0.2	0.20
Maximum	0.875	0.975	0.875	0.975	0.975	0.975

pairs. The 95% CIs were between the ±0.06 used to estimate the sample size. However, health states Q and R showed no statistically significant difference between the values (t-test, $p = 0.589$; Wilcoxon test, $p = 0.645$).

The relation of age, sex, employment, area and social class to health state utility was tested by analysis of variance and t-tests. There were no significant differences in the utility values of the health states based on age, highest education, self-reported health, and work-collar ($p > 0.05$). However, health states Q ($p = 0.006$) and R ($p = 0.042$) were rated significantly lower by males than by females.

The logical consistency of the health state utility valuations was determined by examining the rank of the health state based on the utility score. This is shown in *Table 33*. The mean and median rank for the health state were consistent with the implicit grading of the health states prior to the study, that is the 'worse' health states (health states L, M and N) were ranked fourth and fifth and the 'best' (health states Q and R) were ranked as first.

States valued as worse than death. During the standard gamble exercise health states were valued worse than death on 19 occasions by 17 different respondents. The only two health states where

***TABLE 33** Ranking of health states according to utility score*

	Health state					
	L ***n* (%)**	**M** ***n* (%)**	**N** ***n* (%)**	**P** ***n* (%)**	**Q** ***n* (%)**	**R** ***n* (%)**
1	5 (4.8)	15 (14.3)	5 (4.8)	22 (21.0)	65 (61.9)	72 (68.6)
2	0 (0)	7 (6.7)	1 (1.0)	18 (17.1)	27 (25.7)	23 (21.9)
3	4 (3.8)	12 (11.4)	1 (1.0)	48 (45.7)	8 (7.67)	6 (5.7)
4	27 (26.7)	57 (54.3)	39 (37.1)	13 (12.4)	4 (3.8)	3 (2.9)
5	18 (17.1)	10 (9.5)	42 (40.0)	3 (2.9)	0 (0)	0 (0)
6	50 (47.6)	4 (3.8)	17 (16.2)	1 (1.0)	1 (1.0)	1 (1.0)
Missing	6	6	6	6	6	6
Total	105	105	105	105	105	105
Median rank	5	4	5	3	1	1
25th percentile	4	3	4	2	1	1
75th percentile	6	4	5	3	2	2
Mean	4.9	3.5	4.6	2.6	1.6	1.5
SD	1.3	1.3	1.13	1.1	0.9	0.9

TABLE 34 *Respondents who valued health states worse than death*

	Respondents who ranked health states worse than death	Participants who did not rank health states worse than death	*p*-value
Mean age (years)	38.8 (SD, 17.7)	46.7	0.108
Median age (years)	37	41	
25th percentile	24	28	
75th percentile	55	64	
Sex (%)			0.37
Male	52.9 (*n* = 9)	50	
Female	47.1 (*n* = 8)	50	
Education (%)			0.81
Up to 16 years	32.3 (*n* = 6)	51.3	
Up to 18 years	11.8 (*n* = 2)	9.2	
University	52.9 (*n* = 9)	39.5	
Own health (%)			0.58
Full health	76.5 (*n* = 13)	64.8	
Less than full health	23.5 (*n* = 4)	35.2	
Employment (%)			0.99
Blue collar	22.5 (*n* = 4)	21.0	
White collar	44.4 (*n* = 8)	12.7	
Student	5.6 (*n* = 1)	10.0	
Retired	16.7 (*n* = 3)	25.5	
Unemployed	11.1 (*n* = 2)	27.3	

this occurred were health states L ($n = 17$) and N ($n = 2$). Details of the participants who ranked health states worse than death are shown in *Table 34*. The characteristics of those participants who ranked health states worse than death and those that did not were compared using chi-squared and *t*-tests. No significant differences between the two groups were found though the numbers involved were small.

Sensitivity analysis

One-way sensitivity analysis was carried out on each of the utilities over the 95% CIs. Even at the extremes of these ranges there was no change in the preferred options. Sensitivity analysis was also performed to test the robustness of the utility scores by including or excluding participants who had not valued all of the health states, those where it was unclear whether they were willing to take any risk, those who valued all health states as equal, and those who valued the health states in reverse order from the implicit order.

There were six occasions where there was incomplete valuation of all the states. No significant differences in utility values were found between including all cases or excluding incomplete cases.

Participants unwilling to take any risk. The analysis of utility values in this study assumed that the midpoint (between 100% and 95%) was a proxy for their point of indifference – and hence their utility value. An alternative viewpoint could be that they were valuing the health state as equal to full health (i.e. 1.00).

The total number of health states where this occurred was 20. It was almost exclusively health states Q and R ($n = 17$). The other health states were P ($n = 2$) and M ($n = 1$). However, one individual rated M, P, Q and R this way. There were no significant differences between assuming that utility equals the midpoint or that utility equals 100% (*Table 35*).

TABLE 35 *Comparison of midpoint and risk averse (i.e. valuation of 1) values*

Health state	Mean		Median	
	Midpoint	Risk averse	Midpoint	Risk averse
L	0.32	0.32	0.45	0.45
M	0.56	0.55	0.50	0.50
N	0.46	0.46	0.50	0.50
P	0.70	0.68	0.75	0.75
Q	0.79	0.75	0.80	0.80
R	0.79	0.77	0.85	0.85

Valuation of all health states as the same. This occurred on three occasions with the participants valuing all health states as 0.5. There were no significant differences ($p > 0.05$) in the health state utility values when including or excluding this group of participants.

Participants who reversed the order There were six occasions where health state L was valued as the best health state and health state Q as the worst. These participants tended to be younger than the group as a whole with a median age of 23 years (25th percentile, 18.75; 75th percentile, 27.7).

It can be concluded from the series of sensitivity analysis that where there was doubt regarding the interpretation of values, the numbers were too small to have any influence on the resulting standard gamble values.

Decision trees

Life expectancy

To estimate QALYs it was necessary to have life expectancy data for the health states. Average life expectancy data could not be found from the published literature. Only one study[155] expressed the average life expectancy rather than a mortality rate over time. This study was a case series of amputees and estimated the average life expectancy post-amputation to be 3 years. The treatment of limb ischaemia has changed radically since that time but there is still a very high mortality for amputation.

Patients presenting with acute limb ischaemia and claudication tend to die earlier than average as they have a high cardiovascular mortality, which is two to five times that of the general population.[131] The life expectancy for claudicants in the Frammingham study[158] and Hughson and co-workers,[159] was half of the mean life expectancy of the general population.

The life expectancies used in the study had a number of assumptions.

- It was assumed that the mean life expectancy for the general population was 76.[133,160]
- As the incidence of acute limb ischaemia and claudication increases with age,[158] the life expectancy of a 65-year-old was used as a baseline.
- The average patient in the decision analysis was assumed to have a potential life expectancy of 11 years.
- The life expectancy of palliative care (health state L) was assumed to be between 0.25 and 0.5 years.
- The treatment of claudication would not increase the life expectancy of the patient.

QALYs were calculated by multiplying the average life expectancy by the utility value assigned to the health state. The QALYs associated with each health state are shown in *Table 36*.[131,133,160–164]

Probability values

The probability values used within the decision trees are shown in *Table 37*.[33,34,72,83,106,133,165–171] The baseline values were used to calculate expected utility and expected QALY for each of the branches within the tree. Sensitivity and threshold analysis were performed to test the robustness of the conclusions. The decision

TABLE 36 *Utility values, life expectancy and QALYs*

Health state (95% CI)	Utility values		Life expectancy			QALY	
	Mean	Median	Mean	Low	High	Mean utility	Median utility
L	0.325 (0.26 to 0.39)	0.45	0.375	0.25	0.5	0.12 (0.10 to 0.15)	0.45
M	0.56 (0.52 to 0.5)	0.5	3.5 [160,163]	3	5	1.96 (1.82 to 2.1)	1.75
N	0.45 (0.41 to 0.5)	0.5	3.5 (data as health state M)	3	5	1.58 (1.44 to 1.75)	1.75
P	0.7 (0.66 to 0.73)	0.75	6[161,162]	6	12	4.2 (3.96 to 4.38)	4.5
Q	0.79 (0.76 to 0.82)	0.8	6[161,162]	6	12	4.74 (4.56 to 4.92)	4.8
R:							
Acute limb ischaemia	0.79 (0.76 to 0.82)	0.85	3.85[131,133,160,164]	3	5	3.05 (2.93 to 3.16)	3.27
Intermittent claudication	0.79 (0.76 to 0.82)	0.85	6[161,162]	6	12	4.74 (4.56 to 4.92)	7.65

TABLE 37 *Range of probabilities used in the decision analysis*

Probability variable	Probability		
	Baseline	Range	Reference
30-day mortality	0.071	0.023–0.18	33, 83, 106, 160, 166
30-day amputation	0.091	0.019–0.14	33, 83, 106, 160
Surgery to amputation	0.136	0.025–0.22	83, 106, 167
Surgical success	0.65	0.62–0.68	166, 170
Mobility			
Above-knee amputee	0.4	0.3–0.5	34, 168
Below-knee amputee	0.725	0.67–0.78	34, 168
Primary amputation	0.112	0.028–0.18	169, 170
Amputation mortality	0.25	0.12–0.44	33, 133, 171
Success PTA	0.77	(0.73–0.81)	165, 169, 170
PTA to surgery	0.12	0.11–0.13	72, 166
PTA to amputation	0.335	0.1–0.57	166
Mortality of PTA	0.04	0.00–0.11	165, 166, 170
Claudication			
30-day mortality	0.071		148, 152, 157
30-day amputation	0.091		148, 152, 157
Surgical success	0.65		160
Angioplasty (PTA)			
30-day mortality	0.04		159, 160, 170
30-day amputation	0.335		159
PTA success	0.845	0.72–0.97	151, 160

trees and sensitivity plots are shown in *Figures 4* to *6*.

Tables 38 and *39* summarise the results for the treatment options for critical limb ischaemia and claudication.

For non-salvageable limbs the path, for both above- and below-knee amputation, with the highest expected QALY was primary amputation rather than conservative management. One-way sensitivity analysis showed that the only variable to influence this result was the value of health state N with a threshold value for not amputating equal to 0.099 (i.e. at or near death). This would mean that the majority of the participants of the study (based on utility value) would opt for amputation, except for those who valued being an immobile amputee as worse than death – two interviewees did so in this study.

TABLE 38 *Critical limb ischaemia expected utility and QALY of treatment options*

	Expected utility	Expected QALY
Non-salvageable limb		
Health state L	0.33	0.33
Amputation above knee	0.37	1.32
Amputation below knee	0.40	1.42
Salvageable limb		
Surgery	0.40	1.57
Angioplasty	0.68	3.40

TABLE 39 *Intermittent claudication expected utility and QALY for treatment options*

	Expected utility	Expected QALY
Long-distance claudication		
Conservative treatment	0.79	4.8
Surgery	0.63	3.4
Angioplasty	0.72	4.3
Short-distance claudication		
Conservative treatment	0.70	4.2
Surgery	0.61	4.16
Angioplasty	0.61	4.26

For salvageable limbs the treatment option based on expected utility and expected QALY values would be angioplasty, then surgery and finally primary amputation. The variables that had the most effect on expected QALY values are shown in *Table 40*. Angioplasty mortality of greater than 19% and a success rate of below 33%, meant that surgery became the treatment option of choice. However, the mortality of PTA within the published literature was between 0% and 11% and is, therefore, well below these threshold values.

The next most influential variable is the value of health state R (successful treatment), with a threshold value of below 1.22 QALYs where surgery maximises the expected QALY. Another finding of the sensitivity analysis was that for surgery to be the best option the surgical success must be over 96%. This success rate would be unlikely to be achieved in the clinical situation even with a rigorous selection of patients as the surgical success in the published trials was only between 62% and 68%.

Two-way sensitivity analysis of angioplasty mortality and the QALY value for health state R showed that surgery would be the treatment option at low QALY values for successful treatment (health state R). Two-way sensitivity analysis of surgical mortality and QALY values of health state R showed that surgery maximised QALYs when the value of health state R and surgical mortality are low.

The claudication decision trees (*Figures 5* and *6*) show that for long-distance claudication the preferred treatment option would be conservative treatment, while for short-distance claudication there would be a marginal QALY gain for treatment using angioplasty. However, the differences in the expected QALY for the treatment options within short-distance claudication are within 0.06, and so are unlikely to be clinically significant.

Sensitivity and threshold analysis of the long-distance claudication decision tree showed that the only variable to influence the expected values was the QALY values of conservative treatment (health state Q). The threshold for conservative treatment to be the best option was 4.68 QALYs, below this PTA becomes the best treatment option.

The short-distance claudication decision tree expected outcomes were influenced by the QALY value of conservative treatment (health state P), PTA and surgical success. When conservative treatment was valued above 4.26 QALYs then conservative treatment becomes the best treatment option. Furthermore, surgery also becomes the treatment of choice when the success rate is over 79% (*Table 41*).

Subgroup analysis of those study participants who valued the health states at below the threshold values showed that there was no difference ($p > 0.05$) between demographic features when compared with the whole sample for health state Q or health state P.

TABLE 40 *Threshold values for critical limb ischaemia variables*

	Threshold value	Optimal treatment	Treatment at threshold
Non-salvageable limb		Amputation	
Conservative treatment	None		
Amputation mortality	None		
Mobile amputee	None		
Immobile amputee	0.01	Amputation	Conservative
Salvageable limb		Angioplasty	
Surgical success	0.96		Surgery
Surgical mortality	None		
PTA success	< 0.33		Surgery
PTA mortality	> 0.2		Surgery
Mobile amputee	None		
Immobile amputee	None		
Probability of mobility	None		

TABLE 41 *Claudication decision tree threshold values for probability variables*

	Threshold value	Optimal treatment	Treatment at threshold
Short-distance claudicant			
Conservative treatment	< 4.26	Angioplasty	Conservative
Surgical success	> 0.79	Angioplasty	Surgery
Mortality of surgery	None		
PTA success	None		
PTA mortality	None		
Successful treatment outcome	None		
Amputation variables	None		
Long-distance claudication			
Conservative treatment	< 4.33	Conservative	Angioplasty
Success surgery	None		
Mortality surgery	None		
Success PTA	None		
Mortality PTA	None		
Successful treatment outcome	> 5.28	Conservative	Angioplasty

Discussion

The interviewees who participated in this study were not a reflection of the general population of the UK. The educational achievement was higher and there were more retired and unemployed individuals in the study sample. However, these variables were not shown to have a significant effect on the health state values obtained from respondents in this study.

This lack of significance may have arisen from the comparatively small sample used in the survey. However, recently conducted surveys with larger samples of the general population found that education and employment explained little or none of the variation in health state valuations.[172–174] Furthermore, given the robustness of the findings to large changes in the health state value (see *Results* above), it would not appear that the unrepresentativeness of the sample undermines the key findings of this study.

The no-props variant of the standard gamble method used in this study produced utilities that were logically consistent. The content validity of the health state descriptions appeared to be consistent with the attributes being described in sufficient detail for the participant to distinguish between the individual health states, that is the worst health states had the lowest utility values and the best health states the highest. The health states that described the characteristics of a long-distance claudicant (health state Q) and a post-treatment patient (health state R) were valued as the best health states. The two worst health states were those that described an acute limb ischaemia patient who was in a terminal condition (health state L) and an immobile amputee (health state N).

The utility values generated for the individual health states did have a relatively wide range but the SDs were comparable with published studies that have used the standard gamble method.[175,176] In addition, the 95% CIs around mean health state values were within the range of 0.06 of the *a priori* sample size calculation.

The utilities for the various health states were not significantly related to the demographic characteristics of the study sample. This was probably a reflection of the heterogeneous nature of the sample population and the relatively small sample size. However, Torrance[144] acknowledges that there can be a wide variation in individuals' preferences for health states and that this can not necessarily be explained by demographic characteristics.

The mean and median utility values were different, the mean being less than the median for all the health states, except health state L. The question arises as which should be used? The mean values are a reflection of a whole sample and include all those with extreme values, while median values remove these and are a reflection of the majority.

The mean therefore gives the best estimate of the group as a whole. The aim of this study was to gain societal values for the health states and should include all of society even those with views/valuations away from the majority. This is supported by Feeny and co-workers[147] who advocated the use of mean values and suggests precision can be increased by increasing the sample size.

A potential criticism of the methods employed could be that health states are a stylised over-simplification of the real world. The alternative method would have been to value health scenarios, which provide context and background information. It could be postulated that these would provide the interviewee with more information upon which to make a reasoned decision. However, a long and comprehensive description may provide the person valuing the state with too much information with the result that they may latch on to key phrases.[144]

A limitation of using standard gamble values in the clinical situation is the issue of whether the utility values measured by standard gamble are really a true reflection of people's preferences. The difficulty for people is that often they are valuing abstract, hypothetical conditions which they have not experienced.[155] This can result in them over- or underestimating their ability to cope with a specific situation or condition and hence the utility value associated with that condition.[177]

Two possible criticisms of these methods are that expected utility theory is not a normative description for people's behaviour and standard gamble do not measure people's true preference. However, there does not seem to be a technique available that accurately models people's decision-making behaviour and their true preferences. The two main alternatives currently available are time trade-off and visual analogue scales, and both have their limitations.

Time trade-off produces valuations based on a choice of two certain outcomes with the valuer trading years of life to gain one health state in preference to another.[145] There is doubt as to whether people are really willing to give up a proportion of their remaining healthy years to improve their current health status.[178] In addition, time trade-off does not seem to model the clinical decision-making process as clearly as standard gamble. This is because outcomes are not always certain in the real world and so any model must take into account uncertainty, which time trade-off does not.

Visual analogue scales simply involve participants marking their preference on a line. However, there is a tendency for grouping of health states near the top and bottom, and it does not offer any idea of relative preferences between health states.

There have been two other studies that have obtained utilities for vascular conditions using the standard gamble method.[175,179] However, both interviewed patients and not the general public, and their aim was to compare different methods for obtaining utility values. Bosch and Hunink[175] compared descriptive questionnaire and valuational methods by conducting telephone interviews of patients with intermittent claudication. They obtained a utility value for claudication of 0.85 (SD, 0.18). De Vries and co-workers[179] obtained utility values for claudication that were based on walking distance, with walking distances of greater than 150 m valued at 0.87 (SD, 0.25) and less than 150 m valued at 0.86 (SD, 22).

The values obtained for claudication in these studies were higher than those in the present study. The reason for this was that the participants within the studies (patients with intermittent claudication) were unwilling to take as much risk to extricate themselves from their current situation as the general public in our study. This could be a reflection of claudication being a chronic but relatively benign condition. The claudicants could simply have habituated to their own health state and not wish to take too much risk to return to full health.

The primary difference between this study and previously published studies is that in previous studies the interviewees were not valuing an abstract health state but their own current health state. It would be extremely difficult to relate the utility values associated with health state descriptions to the utility a real person with intermittent claudication attaches to their current health.

The value of using the decision tree approach is in the process of mapping out treatment choices and associated probabilities. It becomes particularly pertinent when, as is the case for acute limb ischaemia and claudication, there is doubt over the most effective treatment. In addition, decision analysis allows extensive sensitivity analysis of any variables used within the model. The model can therefore be rigorously tested and comparisons made with the clinical situation.

Sensitivity analysis showed that health state values affecting the optimal treatment choice within the decision trees were: health states R for acute limb ischaemia, health state Q for long-distance claudication and health state P for short-distance claudication.

The threshold value for health state R of 1.2 QALYs to change the expected result translates to a mean life expectancy of 1.5 years a value outside the range found in the published literature. A conclusion from this could be that the optimal path calculated in the decision tree was the correct one. This was not as clear cut for health state Q where the threshold value translated into a life expectancy of 5.1 years, which was very close to the minimum life expectancy value of 6 years estimated from the literature. The same was true for health state P where the threshold value translates into a life expectancy of 4.5 years. A more exact estimation of life expectancy would therefore be needed to ensure the robustness of the conclusions in these situations.

The sensitivity analysis undertaken within our study also showed that for the critical ischaemia decision tree the variables influencing the treatment path of choice were angioplasty success and mortality. Angioplasty generated the highest expected utility when the mortality was less than 22% and the success rate over 40%. The reported mortality of angioplasty in the published literature was between 0% and 11% and the success rate between 60% and 70%.[165,166,169,170]

However, within these studies the success rate and mortality of angioplasty was dependent on patient selection. It has been estimated that only 25% of lower limb ischaemics are suitable for angioplasty,[169] angioplasty tends to be undertaken only in the less complex lesions and the patients tend to be medically more fit.[180] A further consideration, when reviewing the clinical situation for the treatment of limb ischaemia, should be that the large trials[166,170] do not show any statistical benefit between surgery or angioplasty. However, angioplasty was associated with a lower morbidity.

The decision tree models used within our study, which described the treatment options for critical ischaemia produced results that were consistent with recommendations for current management advocated by the 2nd European Consensus document,[180] which indicate that PTA should be the initial treatment for limb ischaemia if angiography shows that the lesion is suitable.

The treatment options for claudication are a little more clearly defined in that conservative treatment is usually tried first. However, there is no definitive answer of what the treatment option should be at the individual level. A further complication is that claudication can spontaneously improve with no intervention, and this could be a confounding factor within claudication trials.

The decision trees within our study generated the highest expected QALY for the conservative treatment option for long distance claudicants. The expected QALYs for the short distance claudicant treatment options were not significantly different and so no one treatment could be conclusively advocated. The variable influencing this result was the QALY value for conservative treatment, with higher values changing the option to conservative management.

The treatment options generated for claudication would seem to support current practice where conservative treatment is the initial option. There does not seem to be sufficient justification for either surgery or PTA compared with conventional management except where it is severely affecting a person's lifestyle (i.e. low QALY values for the claudication health state).

The message from this study is that the choice of treatment for claudication and limb ischaemia appears to be dependant on obtaining better technical data on effectiveness of the treatment options and on life expectancy estimates.

The decision tree models calculated expected utility and QALY values to recommend treatment options that were consistent with current surgical practise. The results of the decision tree were dependant on the life expectancy used to derive the QALY values and not dependant on the value of the utility attached to the health state. The utility values derived were therefore sufficiently precise but there is a need for a more precise estimation of life expectancy than the one utilised in this study. The study also emphasised the current lack of high-quality evidence available on which to base treatment decisions of acute limb ischaemia and claudication. The literature search, although of only four major databases, produced large numbers of review articles and retrospective studies but few RCTs or systematic reviews.

A further concern was that a number of the randomised trials were dual publications so the evidence was more limited than it first appeared. This meant that the probabilities calculated for the decision tree included only a few RCTs and retrospective studies. However, despite these limitations this study supported current clinical practice and focused on the need for better evidence of key probabilities and life expectancy estimates.

Conjoint analysis

Introduction

In considering the implementation of changes that would improve the provision of vascular surgical services, it is important to elicit the views of users of the services. One way in which this can be done is through the use of descriptive research studies, such as patient satisfaction surveys. However, these studies generally produce similar findings; patients are concerned with factors such as access, waiting times, and continuity of staff.[181] Such surveys have therefore been criticised as providing little useful information to policy makers.[182,183] The problem with such studies lies in the fact that asking people simply to state their level of satisfaction ignores scarcity of resources. Finding out that patients would prefer improvements in most of the factors included in such surveys is of little use when budgetary constraints dictate that it is not possible to provide all the desired improvements. For the purposes of policy decisions, what is required is information on the relative weights that patients attach to the various dimensions of satisfaction and how willing patients are to trade-off these dimensions with one another.[184] A technique that can provide such information is conjoint analysis, which has been specifically designed to examine the impact different attribute have on the overall benefit of a particular good or service. It involves presenting individuals with hypothetical scenarios comprising different levels of the attributes that have been identified as being important and asking respondents to state their preferences for the scenarios. Depending upon the design of the study, respondents can be asked to rank the scenarios, rate them on a scale or choose their most preferred scenario from a series of pairwise choices.

This section describes an application of conjoint analysis to the provision of vascular surgery in North Trent with a view to establishing the trade-offs vascular patients are prepared to make with respect to a number of key attributes of service organisation. The next section briefly describes the conjoint analysis methodology. This is followed by a description of the survey methods. The results of the study precede a discussion of the implications the results may have for the organisation of vascular services.

Methods

The first stage of a conjoint analysis is to identify the relevant attributes of the service to be evaluated. This can be done through a number of methods, which include literature searching, focus groups and seeking expert opinion. Following this, levels have to be assigned to each of the attributes. Similar methods to those used to identify the key attributes can be used. It is an essential requirement that the levels are such that respondents do not regard them as being implausible.

The next stage is the generation of scenario descriptions. The number of scenarios is a function of the number of attributes and levels. If there are A attributes each with L levels, the number of scenarios is given by L^A. If the number of levels varies across the attributes, then the number of scenarios is given by

$$L_1^{A1} \times L_2^{A2} \times \ldots \times L_n^{An}$$

where L_n is the nth level of the nth attribute A_n.

Quite often, the number of scenarios generated can be so large as to preclude each respondent being asked to value every scenario. In such circumstances it can become necessary to reduce the number of scenarios to a more manageable number. In doing so, however, it is crucial that it is done in such a way as to retain the ability to infer preferences for all combinations of levels and attributes. Such conditions can be met through the generation of what is known as a fractional factorial design.

Having reduced the number of scenarios, they are then presented to individuals in the form of a questionnaire. Individuals can be asked to rank the scenarios from most preferred to least preferred, rate them on a rating scale, or choose their most preferred option from a series of pairwise choices. Each method has its respective merits, though it has been argued that from a theoretical basis, pairwise choices are the preferred method.[185]

Data analysis involves the estimation of a regression equation in which the dependent variable is respondent preferences and the independent variables the levels of the attributes of the scenarios. The coefficients on the independent variables can be used to establish a number of different results. First, statistically significant coefficients indicate those attributes that respondents consider to be important. Second, the signs on the coefficients indicate how changes in the attributes affect utility (whether the effect is positive or negative). Third, the relative importance of the attributes can be estimated from the magnitude of their regression coefficients. The magnitude of the coefficients indicates the extent to which utility changes in response to a one unit increase or decrease in the level of an attribute (where utility is a measure of individual preference). The larger the coefficient, the greater the change in utility. Finally, the ratio of the coefficients measures the respondents' marginal rates of substitution between the attributes in the study (i.e. the rate at which they are willing to trade one attribute for another). Specifically, the marginal rate of substitution defines the amount of one attribute individuals are willing to give up to achieve a unit increase in another attribute.

The aim was to develop a conjoint analysis questionnaire that could be administered to vascular patients postally. It was decided to elicit values from patients attending both a teaching hospital, the NGH in Sheffield, and a non-teaching hospital, the Chesterfield and North Derbyshire Royal Hospital (CNDRH). This was done in order to estimate the effect (if any) that hospital location has on patient preferences.

There is a dearth of literature on the preferences of vascular patients regarding service provision. In view of this, a series of interviews was undertaken with a small sample of vascular patients to help establish the attributes of importance. Seven patients were selected at random at the vascular outpatient clinic at the NGH and interviewed in a private room at the clinic. Patients who had a serious vascular condition were omitted from the study to avoid engendering unnecessary anxiety in patients who would already be experiencing significant anxiety. During the interview, the respondent was assisted where necessary with a series of pre-determined questions and prompts. Several common themes emerged from the interviews. These were: accessibility to the hospital in terms of distance; waiting time between diagnosis and treatment; length of stay following an operation; the treatment environment; and accessibility of follow-up services. An attempt was also made to elicit from patients, appropriate levels for each of the attributes mentioned. For example, if the interviewee mentioned waiting time, an attempt was made to gauge what the interviewee considered to be an unacceptable level of waiting time.

In addition to patient interviews, the opinion of several vascular surgeons was sought. This resulted in two further attributes being identified, namely the probability of perioperative death and the probability of the patient needing a limb amputated. The choice of levels for these attributes was based on the opinion and experience of the vascular surgeons.

The attributes and their levels included in the study are presented in *Table 42*.

The number of possible scenarios is 432 (i.e. $3^3 \times 2^4$). These were reduced to a fractional factorial design of 16 scenarios through the use of the computer software package SPEED 2.1.[186]

It was decided to present the scenarios in the form of pairwise choices, the 16 scenarios being randomly paired into eight choices. In order that the scenario descriptions were regarded as plausible to all respondents regardless of their vascular condition, the questionnaire asked all respondents to imagine that they needed to undergo a major vascular operation. In addition to the pairwise choices, respondents were also asked whether they found the questionnaire difficult to complete. Initial discussions with consultants in both Sheffield and Chesterfield suggested that the

TABLE 42 *Attributes and levels included in the conjoint analysis study*

Attributes	Code	Levels
Months between diagnosis and operation	3 6 9	3 months 6 months 9 months
Local or non-local treatment	1 0	Local hospital Different hospital
Chance of not surviving the operation	3 5 7	3 in 100 5 in 100 7 in 100
Chance of needing an amputation	5 8	5 in 100 8 in 100
Length of stay	12 15	12 days 15 days
Whether you see the same or different staff	1 0	Same staff Different staff
Local or non-local follow-up services	1 0	Locally Different location

older cohort of patients with vascular conditions who were to be surveyed might have difficulties completing a questionnaire involving notions such as probability and choice. The full questionnaire is presented in appendix 5.

As indicated above, patients were selected from the NGH and the CNDRH. It was not possible to generate random samples due to characteristics of the data systems at both hospitals. Instead, appointment lists for outpatient clinics were obtained, and patients on the list sent a questionnaire 2–3 weeks prior to their appointment. Reminders were sent to non-responders. In order to avoid sending questionnaires to patients with serious vascular conditions, only those patients who had previously attended an outpatient clinic were selected.

Before commencing the full study, it was decided to pilot the questionnaire on a sample of patients attending the NGH. In line with other conjoint analysis studies, the purpose of the pilot was to assess whether respondents were able to understand the questionnaire and that trading was taking place. A test of internal consistency was also incorporated into the questionnaire. In one of the pairwise choices (Choice 4) the levels of waiting time, probability of perioperative death and probability of requiring an amputation for one scenario were all lower than in the comparator scenario, with the levels of the remaining attribute being equal across scenarios. If respondents did not choose the scenario with the lower levels, this was taken as an indicator that they did not understand the exercise.

Patients were sent the questionnaire prior to their outpatient appointment and asked to bring the completed questionnaire with them to the clinic. Unfortunately, many patients did not remember to do this, resulting in a poor response rate. In view of this it was decided for the main study to ask patients to return the questionnaire in a pre-paid envelope, which was sent with the questionnaire. Despite the poor response rate in the pilot, the small number of responses were sufficient to confirm that the majority of respondents were able to answer the questions in a consistent manner, and that trading between the attributes was taking place. In addition, the absence of negative comments regarding the questionnaire suggested that the questionnaire was not as complex as originally suspected.

Results

Of the 219 questionnaires sent to patients due to attend outpatient appointments at the NGH, 83 were returned following the initial posting. A further 43 questionnaires were returned following the distribution of 134 reminders (two patients had unfortunately died). The response rate for NGH patients was therefore 58%.

A total of 120 questionnaires were sent to CNDRH patients, of which 35 were returned. Unfortunately, a number of adverse responses to the reminder sent to NGH patients led to the decision not to send reminders to CNDRH patients. The response rate for CNDRH patients was therefore a relatively poor 29%, which meant that the overall response rate for the survey was 47%.

Of the 161 questionnaires returned, eight were returned blank, (six from NGH and two from CNDRH) leaving 153 completed questionnaires. Seventy-five per cent of respondents indicated they did not find the questionnaire difficult to complete. Twenty-two per cent found the questionnaire difficult to complete, and 3% did not indicate either way.

Thirty-six respondents failed the test of internal consistency and were dropped from further analysis on the assumption that they had not understood the questionnaire. A further eight respondents had dominant preferences (five with respect to operation mortality and three with respect to probability of amputation). By dominant is meant that respondents always chose the scenario with the lower probability of operation mortality or probability of amputation irrespective of the levels of the other attributes. While dominant preferences indicate a refusal to trade, they are valid preferences. Opinion is divided as to whether or not to include dominant preferences in the analysis or to report them separately.[185,187] In this study, it was decided to report dominant preferences separately.

Thirty-two respondents indicated on at least one occasion that they were indifferent between the scenarios in a pairwise choice. As with dominant preferences, these are valid responses. However, to incorporate them into the analysis would require that the dependent variable be trichotomous. A common technique for analysing data with a multichotomous dependent variable is ordered probit analysis. However, interpretation of the results requires that a distinct ordinal hierarchy is attached to the possible responses. Since it was not possible to do that for the responses in this study (prefer one or other scenario or indifferent), indifferent responses (62 in all) were dropped from the analysis.

A regression equation was initially estimated using a random effects probit model to allow for the possibility of correlation between observations from each respondent. However, as no evidence of correlation was found, an ordinary binomial probit model was subsequently estimated.

An unexpected problem was encountered when attempting to estimate a regression equation. It transpired that there was co-linearity between three of the independent variables. Specifically, the following relationship was identified:

Staff continuity = *f* (location of follow-up services × 1/3 length of stay)

This phenomenon has never before occurred in an application of conjoint analysis in healthcare, and thus it can be regarded as extremely unfortunate that it occurred in this study.

A partial solution to the co-linearity was to estimate three separate regression equations in which only two of the three co-linear attributes were included in each equation. This revealed no difference in the coefficients on the other four attributes and no difference between the log-likelihood and chi-squared statistics. Thus, while the presence of the co-linear relationship means that it is not possible to make any inferences with respect to the three co-linear variables, it is possible do so with the other attributes.

The results of one of three regression equations are presented in *Table 43*. The coefficients on the four non-co-linear attributes are all highly significant. The signs of the coefficients are intuitively what one would expect, that is the positive coefficient on location of treatment suggests respondents prefer to be treated locally, while the negative coefficients on the remaining three attributes are indicative of respondents preferring shorter waiting times and lower probabilities of death and amputation.

TABLE 43 *Results of the binomial probit regression model*

Attributes	Coefficient
Waiting time	–0.1988
Local or non-local treatment	0.8494
Probability of operative mortality	–0.3306
Probability of amputation	–0.2825
Length of stay	*
Continuity of staff	0.9990
Local or non-local follow-up services	0.8586
No. of pairwise choices	823
Log-likelihood	–357.6
Chi-squared	371.1

* *Unable to estimate due to co-linearity*

With respect to the magnitudes of the coefficients indicating the relative importance of the attributes, only those that have been measured in the same units can be meaningfully compared. Thus, only the probability of operative mortality and amputation can be compared. The larger coefficient on the former indicates that it is more important than the latter.

Estimation of the marginal rates of substitution between the attributes reveals that in order to ensure treatment at their local hospital, respondents are willing to: wait an extra 4.25 months between diagnosis and treatment; or incur a 2.57% increase in the probability of operative mortality; or incur a 3% increase in the probability of requiring an amputation.

The above results are presented for patients from both the NGH and CNDRH. However, as indicated earlier the study was designed to investigate whether there are any differences in preference between patients at NGH and CNDRH. To that end the results were segmented by creating dummy variable interaction terms for each of the four non-co-linear attributes. The segmented model is presented in *Table 44*.

As before, all the coefficients are significant and their signs are as expected. However, segmentation reveals that the preference for local treatment is stronger at CNDRH than at NGH. This has important implications for the marginal rates of substitution between treatment location and the other attributes. To ensure treatment at their local hospital CNDRH patients are willing to: wait an extra 5.39 months between diagnosis and treatment compared with 3.97 months for NGH patients; or incur a 4.37% increase in the probability of operative mortality compared with 2.28% for NGH patients; or incur a 4.37% increase in the probability of requiring an amputation compared with 2.74% for patients at NGH.

TABLE 44 *Results from the segmented model*

Attributes	Co-efficient	Significance level
Waiting time		
NGH	–0.199	0.0000
CNDRH	–0.214	0.0000
Local or non-local treatment		
NGH	0.790	0.0000
CNDRH	1.154	0.0000
Probability of operative mortality		
NGH	–0.347	0.0000
CNDRH	–0.264	0.0001
Probability of amputation		
NGH	–0.288	0.0000
CNDRH	–0.264	0.0001
n	823	
Log-likelihood	–353.8	

Discussion

The overwhelming result from this study is the very strong preference patients expressed for receiving treatment at their local hospital. This was particularly pronounced for patients at the CNDRH. Indeed, in view of the willingness of the CNDRH patients to accept over a 4% increase in the risk of perioperative death to be treated at their local hospital, it is tempting to question the validity of the results. However, this study is not the first to find such a result. Finalyson and co-workers[188] conducted a study in which they attempted to assess patient preferences for the regionalisation (i.e. centralisation) of major surgery. They used modified standard gamble questions to establish the additional operative risk 88 patients on a waiting list for elective surgery would be willing to accept to keep services local. They found that 64 patients would be willing to accept additional risk, and that 20 patients would be willing to accept a risk of death at a local centre, which was over 10 percentage points higher than the corresponding risk at the regional centre.

Further evidence in support of the result that patients have such a strong preference for local treatment relative to risk of death can be found in the current study. When establishing the attributes to be included in the conjoint analysis through individual interviews, none of the patients mentioned chances of surviving the operation or risk of amputation. It was only after consultation with vascular surgeons that these two attributes were included.

However, these finding must be considered in the light of the outcome findings reported in chapter 4 (*Use of routine data* and *The relationship between volume and outcome*) and the data in *Table 19*. The responses suggest that additional risks of adverse outcome would be traded for local treatment. However, the magnitude of these risks is actually smaller than may be seen in practice. The failure of patients to identify these attributes may simply reflect a lack of awareness that there may be such large differences in outcome.

That risk of death and amputation were not mentioned by patients exacerbates the problem caused by the co-linearity among the attributes of staff continuity, location of follow-up services and length of stay. The co-linearity problem meant that inferences could not be drawn with respect to three of the five attributes identified as being important by patients. This is clearly far from ideal. As indicated above, this problem is unique among all healthcare conjoint analysis studies conducted to date. The problem could have been identified at the pilot stage by attempting to estimate a regression equation with the pilot data. However, in line with previous conjoint analysis studies, the pilot was used solely to investigate whether respondents were able to understand the questionnaire and that trading was taking place. To prevent a repeat of the co-linearity problem in future conjoint analysis studies, it is recommended that a regression equation is estimated at the pilot stage.

Another potential problem with the current study concerns the generation of the sample. An explicit decision was made to omit those patients who had a serious vascular condition. It could be argued that the values of such patients are extremely relevant to the issue of the provision of vascular services. It is interesting to speculate whether patients with a serious vascular condition would have been quite so willing to accept increases in operation mortality and amputation as the patients in the sample. As discussed above, however, the reason for omitting these patients was to prevent engendering anxiety among a group of patients whose anxiety levels were likely to be high already. To an extent this decision was vindicated in light of the adverse reaction to the reminder letter among a number of patients in the sample (whose vascular conditions, it must be remembered, were considered not to be serious). The omission of patients with serious conditions clearly affects the representativeness of the sample, and consequently the generalisability of the results. The relatively low response rate (albeit largely due to the decision not to send reminders to patients at the CNDRH) also affects generalisability. No data were available on non-responders and as such it is not possible to say whether those who responded are representative of the sample as a whole.

Despite these problems it was encouraging that the majority of responders appeared to understand the questionnaire, as evidenced by the high number of consistent responses. This was particularly encouraging in view of the fact that two of the attributes were probabilistic.

Conjoint analysis is a relatively new evaluative technique in healthcare and there are a number of methodological issues that remain to be resolved.[189] That said, it does have the advantage over more traditional satisfaction surveys in that it provides information on intensity of preference, which is what is required for policy making purposes. With respect to the organisation of the provision of vascular services, the main result from this study is the strong intensity of preference for services to be provided locally. While there are problems with the representativeness of the sample, this result does suggest that any reorganisation of the provision of vascular services in North Trent should take account of patient preferences for local treatment. That this result may be due to the perceived limitations/peculiarities of conjoint analysis as an evaluative technique must be set against the fact that a similar result was found by Finlayson and co-workers[188] using a different evaluative technique.

Chapter 6

Costs and resource use

For the purposes of the operational modelling it is necessary to estimate the resource use and costs relating to the provision of vascular services. Three possible sources of such costs were identified. A review of the literature was carried out to obtain published costs relating to vascular surgery. This was supplemented by an analysis of data that were available locally through routine sources relating to resource usage and cost. Finally, specific primary data collection was carried out, where appropriate to estimate data that were not readily available from the above sources.

Published costs

Introduction

It was the original intention that a review of the literature would be carried out in order to assess the published information regarding the cost of the treatment and consequences of vascular disease. Unfortunately, there were very few data published in a form that was useful in this respect. This review, therefore, concentrates upon issues regarding the reporting of economic studies through a systematic review of literature relating to the costs of vascular services.

Economic evaluation can take many forms, but underlying each is the same basic principle that both the costs and the benefits of alternative uses of resources are measured and valued.[190] The various techniques of economic evaluation are now accepted tools for the appraisal of healthcare programmes, and worldwide there is a growing volume of economic evaluations in the healthcare field.[191–195] That increasing numbers of economic evaluations are being performed and appearing in the literature is a good thing. However, as the literature expands it becomes increasingly important for decision makers to be able to separate the 'good' studies from the 'bad'. To facilitate this quality assessment process, a number of critical appraisal guidelines have been produced.[154,196–200] Most notable among these are those produced by Drummond and co-workers.[154]

While there is undoubtedly a need for such guidelines, the successful application of the critical appraisal criteria embodied within the guidelines is crucially dependent upon the extent to which the study methods and results are reported. If the level of reporting is such that it is not possible to apply all of the critical appraisal criteria, then any judgement regarding the quality of the study is undermined. For example, an economic study may have been performed very well and be methodologically sound, but if the level of reporting is such that third parties cannot assess the validity of the work then the usefulness and potential impact of the study is significantly diminished. The extent to which this occurs is a function of the information omitted. Other things being equal, the more inadequate the reporting, the less one is able to judge the quality of a study and consequently the less confidence one has in the study's results and recommendations. In effect, adequate reporting of economic studies can be regarded as a prerequisite for an assessment of a study's quality.

The importance of establishing reporting guidelines for economic studies has recently been acknowledged,[201,202] and such guidelines have started to appear.[203–205]

In view of the importance of reporting standards to the overall assessment of the quality of economic studies, the aim of this paper is to investigate the extent of reporting in the area of peripheral vascular surgery. To facilitate this aim, a systematic review of the journal literature between 1986 and the first half of 1997 was undertaken in order to identify relevant economic studies. Strictly speaking, an economic evaluation con-siders both costs and benefits. However, in practice, many studies do not tackle the more complex assessment of benefit, but rather focus on cost issues only. In order to generate sufficient articles from the review, therefore, we have defined 'relevant economic studies' as those that have attempted to measure costs. While the measurement of costs alone is not ideal, such studies can still provide useful information (though it should be noted that any recommendation between treatment options should ideally be based on an assessment of costs **and** benefits).

The next section presents a description of the search strategy followed by the reporting guidelines used to assess each of the studies identified in the search. The results of the systematic review and application of the guidelines are then presented. A discussion of the main findings and their implications follows before offering some concluding comments.

Methods

Search strategy

The aim of the search was to identify articles that focus on the cost implications of peripheral vascular surgery. The main databases used were MEDLINE, EMBASE (*Excerpta Medica*), Science Citation Index and Social Science Citation Index (all via the BIDS service), HealthSTAR, DHSS-DATA, HELMIS (Nuffield Institute for Health, University of Leeds) and the Cochrane Library. The databases were searched back to 1986 (it was anticipated that the return in terms of relevant articles identified prior to 1986 would be small relative to the research costs of extending the search period). Relevant citations from retrieved articles were identified once these articles had been retrieved and scrutinised. The keywords used in the search are listed in appendix 2.

A number of exclusion criteria were used in the selection of the articles. An article was rejected if it conformed with one or more of the following criteria: it was not written in English; it was not published in a journal; it was an editorial, a letter or an abstract; the procedures in the article were not relevant to peripheral vascular surgery; there was no original data collection regarding resource use; the cost data presented were hospital charges or payments (hospital charges or payments do not necessarily reflect actual resource use).

The abstracts of the articles identified by the search were read, and those articles that could definitely be rejected on the basis of the above criteria were excluded. The remaining articles were obtained and read. Further application of the exclusion criteria resulted in the identification of all relevant articles to be included in the review. Various summary information was extracted from the articles before subjecting them to scrutiny of their reporting quality.

Reporting guidelines

In order to assess the extent of reporting in the studies identified in the review, the reporting guidelines put forward by the British Medical Journal (BMJ) Economic Evaluation Working Party were used.[203] It was decided to use these guidelines in preference to other available guidelines for the following reasons. First, they are directly based on the critical appraisal guidelines developed by Drummond and co-workers.[154] As alluded to above, these critical appraisal guidelines are the most well known and widely used in health economics and have formed the basis of many subsequent sets of guidelines developed by others. Second, unlike some guidelines, the BMJ guidelines are not pharmaceutical specific. Rather, they have been developed with the intention of being generally applicable. Finally, they are the least prescriptive of the available guidelines. This last point is, in our opinion, particularly important in that there is a danger that overly prescriptive guidelines can discourage the development of innovative methods in economic studies. In drawing up their guidelines, the BMJ Working Party was aware of this potential problem:

> "It was not our intention to be unduly prescriptive or stifle innovative methods; our emphasis is on improving the clarity of economic evaluations." (Drummond and co-workers, p. 275.[203])

The guidelines are presented under ten headings and are designed to be applied to full economic evaluations in which the costs and consequences of at least two healthcare interventions are compared. However, 'partial' evaluations, such as costing studies, are also catered for in that the relevant sections of the guidelines can be applied to such studies.

The guidelines specific to costing are as follows.

- Quantities of resources should be reported separately from the prices (unit costs) of those resources.
- Methods for the estimation of both quantities and prices (unit costs) should be given.
- The currency and price date should be recorded and details of any adjustment for inflation, or currency conversion, given.

In addition to the above criteria, a fourth general guideline is relevant to costing exercises and relates to the need to allow for uncertainty in costs estimates by carrying out a sensitivity analysis. The BMJ Working Party guideline on sensitivity analysis states that:

- when a sensitivity analysis is performed details should be given of the approach used, for example multivariate, univariate, threshold analysis, and justification given for the choice of variables for sensitivity analysis and the ranges over which they are varied.

The above four guidelines were applied to the studies included in the review with a view to assessing their reporting quality.

Results

Following the application of the exclusion criteria to the articles identified in the literature search, 30 articles remained for inclusion in the review.

For each of the 30 studies,[167,206–234] *Table 45* summarises the study condition, the country in which the study took place, the year of publication and the type of study on which the costing exercises were based. It is interesting to note that only one of the 30 studies was published before 1990, and that over half (17 studies) were published in the last 2 1/2 years of the search period. This pattern is indicative of the relatively recent growth in economic studies and vindicates our decision not to extend the search period back before 1986.

TABLE 45 *Study condition, country, year and study type*

Reference	Condition	Country	Year	Study type
167	PAOD: critical ischaemia	UK	1995	Prospective & retrospective
206	Not specified	USA	1993	Survey of vascular labs
207	Stroke prevention	USA	1997	Retrospective
208	AAA	USA	1991	Retrospective
209	PAOD: critical ischaemia	UK	1992	Prospective
210	Stroke prevention	USA	1997	Modelling
211	PAOD: critical ischaemia	UK	1994	Retrospective
212	PAOD: general	USA	1993	Randomised trial
213	PAOD: critical ischaemia	Sweden	1996	Retrospective
214	Not specified	USA	1993	Prospective
215	Preoperative examination in aorta, pelvis and lower limbs	Sweden	1996	Prospective
216	Stroke prevention	UK	1990	Prospective
217	PAOD: critical ischaemia	UK	1995	Retrospective
218	Chronic venous insufficiency	USA	1997	Prospective
219	PAOD: general and critical ischaemia	UK	1986	Prospective
220	PAOD: general	USA	1996	Prospective
221	Stroke prevention	USA	1995	Prospective
222	PAOD: general	France	1994	Prospective
223	PAOD: critical ischaemia	Norway	1996	Prospective
224	PAOD: critical ischaemia	UK	1997	Prospective
225	PAOD: critical ischaemia	UK	1997	Prospective
226	Stroke prevention	Australia	1995	Retrospective
227	PAOD with diabetes	New Zealand	1992	Retrospective
228	PAOD: critical ischaemia	New Zealand	1994	Retrospective
229	PAOD: general	UK	1996	Modelling
230	PAOD: critical ischaemia and acute ischaemia	UK	1996	Prospective
231	PAOD: general	USA	1992	Retrospective
232	PAOD with diabetes	New Zealand	1993	Retrospective
233	Stroke prevention	Finland	1995	Prospective
234	PAOD: short femoro-popliteal occlusions	The Netherlands	1995	Retrospective

PAOD, peripheral arterial occlusive disease (There is inevitably a degree of overlap between the PAOD sub-categories.)

The 30 studies were undertaken in nine different countries, with the majority taking place in the UK and the USA. Interestingly, nine of the ten studies from the UK focused on peripheral arterial occlusive disease, with eight of these focusing specifically on limb ischaemia. This contrasts with the studies from the USA, which covered a wider range of conditions.

With respect to the costing exercises, 14 involved prospective data collection, 11 involved retrospective data collection and one involved a combination of both. Perhaps surprisingly, only one study involved a randomised trial. Of the remaining three studies, two were modelling exercises and the other involved a postal survey of vascular laboratories. With respect to the modelling studies, it might be thought that applying the costing guidelines to them is inappropriate, particularly as the BMJ guidelines contain a section specific to modelling exercises. However, both studies include cost estimates in their models, and as such we would argue that the application of the costing guidelines is therefore merited.

The procedures costed in the studies are presented in *Table 46*. Reconstruction/by-pass/revascularisation were the most commonly costed procedures (12 studies), followed by amputation (11 studies). The other procedures that were costed in more than one study are duplex/Doppler ultrasound (seven studies), angioplasty (five studies), CE (four studies), angiography (three studies) and the treatment of diabetic peripheral arterial occlusive disease (two studies).

We have chosen not to report the actual cost estimates from the studies. The reason for this is that the cost estimates alone are effectively meaningless without knowing the details of how they were calculated. Numerous factors can affect cost estimates, such as whether the costs are total, average or marginal, the perspective of the study, whether allowance has been made for differential timing of costs through the application of discounting, and other key assumptions. Single estimates of cost should not be taken at face value without first assessing the methods used to produce the estimates.

The results of applying the BMJ reporting guidelines to the 30 studies are summarised in *Table 47*. (It should be noted that in the table, the guideline, which refers to the methods for

TABLE 46 *Procedures costed by study*

Procedure costed	Reference
Investigations	
(A) Duplex/doppler ultrasound	206, 207, 214, 215, 216, 221, 233
(B) Angiography	215, 221, 233
(C) CT scan	233
Surgical procedures	
(D) Reconstruction/by-pass/revascularisation	167, 209, 211, 213, 217, 219, 220, 223, 224, 225, 229, 230
(E) Thromboendarterectomy	234
(F) Amputation	167, 211, 213, 217, 219, 223, 224, 225, 228, 229, 230
(G) CE	207, 210, 221, 226
(H) AAA repair	208
(I) Subfascial endoscopic perforator surgery	218
Endovascular procedures	
(J) Angioplasty	167, 213, 219, 229, 230, 234
Drug treatments	
(K) Iloprost	228
(L) Pentoxyfilline	231
(M) Cefamandole and cefazolin	212
Other	
(N) Treatment of diabetic peripheral arterial occlusive disease	227, 232
(O) Not specified	222

TABLE 47 *Critical assessment of costing methodologies*

Reference	Quantities of resources reported separately from price	Methods of estimating quantities given	Methods of estimating prices given	Year of prices given/currency		Sensitivity analysis performed	Procedure costed*
167	Yes	Yes	No	No	UK£	No[c]	D, F, J
206	Yes	Yes	Yes	No	US$	No	A
207	No	No	No	No	US$	No	A, G
208	No	No	Yes	No	US$	No	H
209	No	Yes	Yes	1989	US$	No	D, F
210	No	Yes	Yes	1996	US$	Yes	G
211	No	Yes	No	1989	UK£	No[a]	D, F
212	Yes	Yes	Yes	No	US$	No	M
213	Yes	No	Yes	1996	US$	No	D, F, J
214	Yes	Yes	Yes	No	US$	Yes	A
215	No	No	No	1993	SEK	No	A, B
216	No	Yes	Yes	No	UK£	No	A
217	No	No	No	No	UK£	No	D, F
218	No	No	No	No	US$	No	I
219	No	Yes	Yes	1984	UK£	No[b]	D, J
220	No	Yes	Yes	No	US$	No	D
221	No	No	Yes	1993	US$	Yes	A, B, G
222	No	Yes	No	No	US$	No	O
223	No	No	No	No	UK£	No	D, F
224	No	Yes	No	No	UK£	No	D, F
225	No	Yes	Yes	1994–95	UK£	No	D, F
226	Yes	Yes	Yes	No	Aus$	No	G
227	No	Yes	Yes	1989	NZ$	No	N
228	No	Yes	Yes	No	NZ$	No	F, K
229	No	Yes	Yes	1993–94	UK£	Yes[d]	D, F, J
230	Yes	No	Yes	No	UK£	No[e]	D, F, J
231	No	Yes	Yes	1989	US$	No	L
232	Yes	No	Yes	No	NZ$	No	N
233	No	No	Yes	1994	US$	No	A, B ,C
234	No	Yes	Yes	1990	DGL	Yes[f]	E, J

* See Table 46 *for classification of procedures*

[a] *Range given for amputation costs*
[b] *Range given for length of stay*
[c] *Range given for some costs*
[d] *On one cost only*
[e] *Inter-quartile ranges given for some costs*
[f] *Details not given*

the estimation of quantities of resources and their prices, has been split into two.) With respect to costing guidelines, the studies perform best in terms of reporting the methods of estimating prices and quantities of resources. Twenty-one studies provided information on prices, while 19 reported quantity of resources information. When it comes to reporting quantities of resources separately from price, however, the studies perform less well with only eight of them conforming to this guideline. The studies can also be criticised for not stating the year in which the prices are given, with 17 omitting this information.

The studies perform quite well in terms of the sensitivity analysis guideline in the sense that when a sensitivity analysis was performed, details were reported in all but one case. However, if one judges the group of studies in terms of the number undertaking a sensitivity analysis, then they can be said to perform poorly as only five of them did so. Of course, whether or not a study undertakes a sensitivity analysis is not covered by the reporting guidelines. However, in view of the importance of sensitivity analysis, we feel the dearth of such an exercise among the studies is worthy of note.

Discussion

It has been argued that adequate reporting in economic studies is a prerequisite for judging the quality of such studies. Inability to apply critical appraisal criteria due to inadequate reporting can significantly diminish the usefulness and potential impact of an economic study. Even if it is somehow known that an economic study is methodologically sound, inadequate reporting still presents a problem in that it hinders the ability of individuals to judge the applicability of a study's results and methods to their own (different) set of circumstances/conditions.

Having applied the BMJ reporting guidelines to the vascular costing studies identified in the review, it is tempting to criticise the studies for reporting deficiencies. However, it would be unfair to do so without first comparing them to costing studies in other clinical areas. Unfortunately, we are unable to do this as we do not know of any other studies that have applied reporting guidelines in this way. That said, some indication of the extent of economic reporting in other area can be gleaned from Mason and Drummond[201,235] and Balas and co-workers.[236]

Mason and Drummond[201,235] comment on the results of a critical appraisal of 147 economic evaluations contained on a register of cost-effectiveness studies held by the Department of Health in England. While the focus of the appraisal was not reporting standards, some reference is made to reporting. For instance, they indicate that they found considerable variation in the basic standard of reporting among the 147 studies. They specifically mention that the year to which the cost data relate was ambiguous in around 25% of the studies. They also state that it was impossible to assess the quality of many of the studies due to inadequate reporting, and recommend that in future, economic studies should conform to a minimum reporting standard.

Balas and co-workers[236] reviewed the medical literature with the aim of identifying and critically appraising clinical trials containing economic analysis. As with Mason and Drummond[201,235] their focus was not reporting standards. However, they did find sufficient deficiencies in reporting to state that the limitations they found in the studies they reviewed should act as a warning to practitioners and administrators who routinely make recommendations and inferences based on incomplete information.

It would seem from the above (admittedly limited) evidence that reporting inadequacies are a potential problem in not just PVD, but also many other clinical areas. While this is a cause for concern, it should be set against the fact that it is only relatively recently that reporting guidelines have been published. What would be more of a concern would be if this study was repeated 10 years hence and no improvement in reporting was found. It is to be hoped this will not be the case.

The original intention of reviewing the data regarding the costing of vascular procedures was to obtain published figures that would supplement the local data in estimating the likely cost of reconfiguration of services. Due to the considerations above, the data identified have not been felt to be of sufficient reliability to be used in this way.

Resource use

For the purpose of estimating cost and resource implications of changes in service configuration the resources have been broken down into four categories: theatre time, inpatient stay, ITU costs, and costs of radiology. For each of these an estimate of resource use was made and estimates were made of a cost per unit value, as appropriate to each resource.

The approach was to undertake an original analysis of routine data rather than collect new data. The rationale for this approach was to enable the results to be generalisable outside of South Yorkshire and to ensure the results can be used in the model. The casemix classification (see chapter 3, *Suggested casemix groupings*) was limited by available data collection systems and hence it was not possible to undertake as detailed a level of analysis as would have been ideal. The resource units used in the costing were therefore limited to routinely produced ward stay, ITU stay, time in theatre and use of radiology for the key casemix groups used in the model. The estimation of unit costs was undertaken using best available local financial data, but the resource use data are presented separately so that local cost data may be used to adapt the findings for other circumstances.

Theatre time

The OPCS codes for the full range of relevant vascular procedures were classified into 11 'clusters' corresponding to the casemix groups. The data used did not contain information regarding the method of admission and it was, thus, impossible to produce timings corresponding exactly to the casemix definitions. In the case of aortic and reconstructive surgery the OPCS codes for emergency procedures were used. As discussed in chapter 3 (*Suggested casemix groupings*) these do not correspond exactly to the definitions used due to the discrepancy between emergency admissions and emergency procedures. However this was the best estimate available and the overall differences are small. In the case of amputations there are no separate codings for emergency procedures and all cases were aggregated to produce an average. The clusters were defined as follows:

- supra-renal aortic and visceral artery surgery
- emergency aortic surgery
- elective aortic surgery
- carotid surgery
- upper limb surgery
- femoro-distal bypass
- emergency vascular reconstruction
- elective vascular reconstruction
- minor amputation
- major amputation
- varicose veins.

Operating theatre data were obtained from a teaching hospital and a DGH. These data recorded the time spent in anaesthesia, the operation and recovery for every vascular procedure (as defined in chapter 3) performed in the teaching hospital between April 1990 and October 1997 and every vascular procedure performed in the DGH between April 1996 and March 1997. For each cluster, the mean 'theatre time' (anaesthesia, operation and recovery) with 95% CIs were calculated for each hospital type (*Table 48*).

Data were available for all of the clusters at the teaching hospital. This is in contrast to the DGH where data were available for only four clusters (elective vascular reconstruction, minor and

TABLE 48 *Mean theatre times per cluster (95% CI) for the Sheffield and the DGH*

Cluster	Theatre times (minutes)	
	Sheffield	**DGH**
Supra-renal aortic and visceral surgery	355	No data
Emergency aortic surgery	214 (181 to 247)	No data
Elective aortic surgery	262 (241 to 283)	No data
Carotid surgery	149 (140 to 158)	No data
Upper limb surgery	108 (83 to 133)	No data
Femoro-distal bypass	260 (98 to 368)	No data
Emergency vascular reconstruction	174 (134 to 215)	No data
Elective vascular reconstruction	173 (164 to 182)	185 (132 to 237)
Minor amputation	51 (42 to 61)	48 (38 to 59)
Major amputation	96 (83 to 109)	127 (110 to 144)
Variscose veins	54 (51 to 58)	62 (65 to 69)

major amputations and varicose veins). The mean theatre times for major amputations and varicose veins are statistically significantly shorter at the teaching hospital than at the DGH. Comparisons between the elective vascular reconstruction and minor amputations reveal no statistically significant differences.

These data have been analysed on the basis of individual procedures. As shown in chapter 3 (*Secondary procedures*), there are a significant proportion of repeat procedures in some casemix categories. The total theatre time associated with each casemix group has been evaluated by calculating the proportion of patients undergoing additional procedures (as shown in *Tables 16* and *17*) and summating the additional theatre time for these procedures. The resulting total theatre time per admission is shown in *Table 49*. These figures have been based upon the teaching hospital data, as they were the only complete data available.

Inpatient stay

The hospital length of stay was calculated for each of the casemix groups at each participating provider unit. The mean length of stay and SD are given in *Table 50*. In calculating length of stay for contractual purposes, 'trimmed' data are sometimes used in order to exclude cases with exceptionally long stays that may distort the figures. In the current situation it is felt to be preferable to use untrimmed data in order to account for the resources required for such cases. It is unlikely that individual exceptional cases have a significant impact on most of the groupings as they are based on fairly large samples. However, some of the less common casemix groups may suffer from this problem. For example, the average length of stay for supra-renal aortic surgery in Doncaster is 69 days, but this is based on a single case. For this reason, estimates based upon fewer than five cases have been replaced by the average for all of North Trent for use in the model.

ITU

The main database does not contain information regarding length of stay on ITU or HDU. The only data available were from an internal audit system at the NGH. This provided estimates for the length of stay (in hours) in each unit. Unfortunately the coding system did not allow accurate separation of casemix groups and the best that could be obtained was a total for emergency and elective admissions to ITU/HDU of aortic cases, vascular reconstructions, amputations and carotid surgery. These have been averaged over the total number of known cases in each category (including femoro-distal bypass with the reconstructions) and the estimates are given in *Table 51*.

One problem with dealing with high-dependency facilities is that the level of facilities available

TABLE 49 *Theatre time by casemix group including secondary procedures*

Casemix group	Primary procedure (minutes)	Total time (minutes)
Supra-renal AAA	355	452.7
Aortic – elective	262	273
Aortic – emergency	214	220.1
Carotid	149	151.7
Upper limb	108	125.3
Major amputation – emergency	96	175.4
Femoro-distal – emergency	260	435.6
Reconstruction – emergency	173	199.7
Minor amputation – emergency	51	54.02
Angioplasty – emergency		0
Angiography – emergency		0
Major amputation – elective	96	155.7
Femoro-distal – elective	260	317.8
Reconstruction – elective	174	189.9
Minor amputation – elective	51	51.88
Angioplasty – elective		0
Angiography – elective		0
Varicose veins	54	54.24

***TABLE 50** Mean (SD) length of stay for each casemix group and provider unit*

	Barnsley	Doncaster	North Derbyshire	North Nottinghamshire	Rotherham	Sheffield	Total
Supra-renal AAA	5.00*	69.00*	15.00*			12.10 (12.71)	13.68 (16.99)
Aortic – elective	13.07 (18.89)	13.88 (15.89)	10.67 (10.98)		9.50 (11.50)	12.96 (11.93)	12.69 (13.13)
Aortic – emergency	12.50 (8.07)	14.02 (9.04)	11.85 (5.79)		18.11 (8.20)	15.54 (21.14)	14.44 (15.34)
Carotid		7.00*	5.00*		7.00*	8.13 (10.59)	8.09 (10.45)
Upper limb	7.25 (4.79)	2.00*	10.90 (5.63)		3.50*	9.71 (8.81)	9.00 (7.39)
Major amputation – emergency	32.02 (23.16)	23.21 (19.80)	25.79 (20.96)	29.00 (28.78)	37.24 (24.31)	31.71 (23.93)	29.46 (22.99)
Femoro-distal – emergency	47.00*	43.00*	38.00*		37.00*	32.65 (33.96)	34.21 (30.61)
Reconstruction – emergency	16.10 (14.73)	22.89 (17.93)	23.13 (16.18)	5.00*	12.76 (12.46)	19.31 (19.45)	19.63 (18.31)
Minor amputation – emergency	19.67 (22.58)	15.12 (16.13)	29.53 (24.98)	11.59 (11.39)	24.77 (29.55)	12.52 (18.60)	14.57 (19.43)
Angioplasty – emergency	18.67*	11.17 (8.88)	15.21 (15.63)		17.63 (12.00)	14.34 (14.24)	14.01 (13.30)
Angiography – emergency	14.64 (13.89)	11.73 (10.03)	15.95 (14.24)		10.57 (7.04)	17.22 (20.58)	15.92 (18.34)
Major amputation – elective	24.20 (17.44)	16.25 (11.11)	24.48 (14.43)	6.00 (5.29)	19.33 (5.35)	26.07 (24.47)	23.11 (19.33)
Femoro-distal – elective	12.50*	15.00*				27.63 (21.06)	25.50 (20.02)
Reconstruction – elective	12.91 (9.93)	9.92 (7.00)	13.71 (9.49)		17.17 (9.61)	14.15 (13.97)	13.51 (11.76)
Minor amputation – elective	3.42 (3.44)	2.12 (4.16)	3.44 (6.54)	1.92 (3.87)	4.41 (5.72)	7.69 (13.25)	4.99 (9.64)
Angioplasty – elective	3.07 (3.42)	2.08 (3.02)	2.08 (5.44)		2.07 (2.50)	3.20 (8.16)	2.69 (6.33)
Angiography – elective	2.36 (1.64)	2.13 (3.82)	2.50 (7.61)		1.55 (3.04)	1.79 (6.02)	1.89 (5.48)
Varicose veins	1.09 (0.85)	0.98 (1.12)	1.29 (1.01)	0.84 (0.43)	0.86 (2.96)	0.79 (2.30)	0.95 (1.82)

* *Based on a sample of less than five cases*

differs between centres. Several centres do not have HDU beds available and will thus tend to use ITU for all patients requiring such facilities. For this reason the modelling has used a single total figure for all high-dependency requirements. For costing purposes the split between HDU and ITU in *Table 51* has been assumed as described below.

***TABLE 51** Average time spent in ITU or HDU*

Casemix group	ITU (hours)	HDU (hours)
Aortic – elective	27.47	27.75
Aortic – emergency	98.74	18.6
Carotid	2.17	18.91
Major amputation – emergency	17.17	2.15
Reconstruction – emergency	2.16	1.81
Major amputation – elective	6.2	4.19
Reconstruction – elective	4.47	3.67

Radiology

The number of interventional vascular radiology procedures for each casemix group has been approximated using the data in *Table 16* and *17*, which include both primary and secondary procedures. Only two categories of radiology procedures have been considered: angiography and angioplasty. The latter is assumed to include all interventional therapeutic transluminal procedures. It is recognised that there are a number of procedures with differing resource implications. However, the current coding systems do not allow such procedures as insertion of stents and thrombolysis to be separately identified and so these are included with other therapeutic procedures. The number of procedures per casemix group is given in *Table 52* along with the proportion that are therapeutic.

A single combined average has been used for all districts in the model. Although there are consider-

TABLE 52 *Number of angiographic procedures per admission for each casemix group and proportion of therapeutic procedures (i.e. excluding diagnostic angiography)*

	No. of procedures	Proportion therapeutic (%)
Supra-renal AAA	0.11	0
Aortic – elective	0.04	25
Aortic – emergency	0.05	0
Carotid	0.05	0
Upper limb	0.16	0
Major amputation – emergency	0.46	41
Femoro-distal – emergency	0.94	18
Reconstruction – emergency	0.75	27
Minor amputation – emergency	0.15	40
Angioplasty – emergency	1.74	33
Angiography – emergency	1.18	0
Major amputation – elective	0.31	43
Femoro-distal – elective	0.49	0
Reconstruction – elective	0.26	32
Minor amputation – elective	0.10	60
Angioplasty – elective	1.26	42
Angiography – elective	1.12	0
Varicose veins	0.00	0

able differences in the rates of these procedures across North Trent, the proportion of each casemix category undergoing secondary radiological procedures does not appear to vary greatly and the use of individual rates is subject to inaccuracies due to the small sample sizes concerned. There are, however, known to be differences in the use of stents and thrombolysis as described in chapter 2 (*Survey of participating districts*). The implications of this will be discussed below.

Outpatients visits

The lack of a suitable coding system for outpatient visits means that it is not possible to accurately identify the number of visits associated with specific casemix categories. The estimates for total number of visits for each casemix group, including visits of new patients, not associated with an inpatient episode have been approximated through the consultant interviews described in chapter 2 and expert opinion. The estimates used in the model are given in *Table 53* and have been reconciled with the known total number of outpatient visits at NGH, as described below. This is not possible for other centres as in all cases there are joint general and vascular clinics and there is no information that will allow the visits related to vascular cases to be separately identified.

TABLE 53 *Number of outpatient visits per admission for each casemix group as estimated from consultant interviews*

	Outpatient visits
Supra-renal AAA	3
Aortic – elective	3
Aortic – emergency	3
Carotid	3
Upper limb	3
Major amputation – emergency	3
Femoro-distal – emergency	3
Reconstruction – emergency	3
Minor amputation – emergency	3
Angioplasty – emergency	3
Angiography – emergency	3
Major amputation – elective	3
Femoro-distal – elective	3
Reconstruction – elective	3
Minor ampuation – elective	3
Angioplasty – elective	2
Angiography – elective	2
Varicose veins	1

Local costs

Detailed cost information was not available from the majority of centres. There has recently been publication of some cost information in the 1998 Reference Costs[25] and the specific data contained on the CD-ROM relating to the hospitals in North Trent has been examined. This information is very patchy and covers only a few of the relevant HRGs in most hospitals. Costs within vascular surgery at the NGH have recently been the subject of a detailed analysis and information obtained from this work has been used for the estimation of approximate costs of the reconfiguration of services. Costs for the major resource drivers have been obtained using methods as described in the *NHS Executive guidance and costing manuals*. This has produced estimated costs for vascular admissions for ward, HDU and ITU bed-days, theatre minutes, angiography and angioplasty procedures and outpatient visits.

These costs are based upon a 'top down' approach in which all the direct and indirect costs are allocated to the resource to which they are most closely related and apportioned on the basis of the known total usage for that resource. *Table 54* gives the estimated resource costs and total resource use based upon the 1997–98 financial year for the relevant resources relating to vascular services at the NGH. The table also shows, for comparison, the estimated use of resources from the base case model. As can be seen, the model appears to produce higher estimates for the use of most resources, particularly the use of angiography and angioplasty. Some of these discrepancies can be explained by known differences in the assumptions made.

TABLE 54 *Resource unit costs (£) estimated resource use from NGH data and from modelling*

Unit	Unit cost	Resource use	Estimate from model
Bed-days	207	11,239	14,658
HDU days	447	218	216
ITU days	1262	317	382
Theatre minutes	8.37	104,233	148,570
Angioplasty procedures	925	269	474
Angiography procedures	347	471	831

In the case of radiological procedures the estimate from the model is close to that given by the figures for activity from the angiography suite. The lower estimate given by the finance department is due to the fact that such procedures are only included in their calculations if they are coded as the primary procedure. The method of costing uses a 'fully absorbed' cost in which all the staff, disposable, capital charges and overheads for the angiography suite are apportioned to the recorded number of procedures. The effect of this is to inflate the price of angiography procedures and reduce the cost of admissions for other procedures where angiography is carried out as a secondary procedure.

In the case of bed-days and theatre time there is known to be missed activity as the financial data are based upon the known activity of the vascular unit, whereas the casemix definitions will include some activity that will be ascribed to other services, such as varicose vein surgery under the care of general surgeons and procedures carried out on diabetic patients under the care of medical specialists. Another source of possible discrepancy is the different assumptions made in calculating resource use. For example the bed-days on ITU are based upon midnight occupancy for the financial data and based upon hourly occupancy for the model.

There is, therefore, some doubt about the costs as there remains a discrepancy after correcting as far as possible for these errors. It is not clear whether such errors arise from differences in counting methods or through allocation of resource use to another speciality. The method of costing means that the latter is unlikely to affect unit cost, whereas the former will result in inflated costs due to apportionment to the total expenditure to an underestimate of total resources used. *Table 55* gives corrected

TABLE 55 *Corrected resource unit costs (£) estimated resource use from NGH based on differing assumptions of model*

	Corrected costs (£)
Bed-days	183–207
HDU days	447–451
ITU days	1047–1262
Theatre minutes	6.71–8.37
Angioplasty procedures	525
Angiography procedures	197

estimates of costs, using a range where significant doubt remains.

The estimated costs and resource use have been used to provide approximate costs for the casemix groups and the results are shown in *Table 56*. It is not possible to give exact comparisons with published reference costs, as the casemix definitions are different. The poor quality of routinely collected data in this respect is a cause for concern. An examination of some corresponding categories suggests that the model gives a higher estimate of cost for major vascular procedures and a lower estimate for minor procedures such as elective varicose veins and angiography. This may be due to the more accurate allocation of high-dependency costs and secondary procedures to the appropriate categories.

TABLE 56 *Estimated total costs per case for casemix groups based upon resources used for modelling and estimated minimum and maximum resource use costs*

	Total costs (£)
Supra-renal AAA	4645–5604
Aortic – elective	5873–6880
Aortic – emergency	8176–9696
Carotid	2996–3469
Upper limb	3265–3787
Major amputation – emergency	7886–9088
Femoro-distal – emergency	9502–11060
Reconstruction – emergency	4899–5672
Minor amputation – emergency	3923–4474
Angioplasty – emergency	2650–2922
Angiography – emergency	3413–3821
Major amputation – elective	5870–6759
Femoro-distal – elective	5159–6077
Reconstruction – elective	3689–4317
Minor amputation – elective	2431–2785
Angioplasty – elective	949–995
Angiography – elective	390–413
Varicose veins	499–607

Chapter 7
Operational modelling

Scenarios for care

The models of care for the provision of vascular services that have been considered are based upon the current British system in which vascular surgery has developed as a sub-speciality of general surgery. Patients tend to be referred to vascular surgeons for assessment, with multidisciplinary cooperation taking place between the surgeons and specialist radiologists. The models of care that are to be considered revolve mainly around the degree to which centralisation and sub-specialisation have taken place. Thus, the extremes are a fully centralised service in which all cases are referred to a major centre, and a fully devolved service in which they remain an integral part of the general surgical service in all hospitals with such services.

There are, however, alternative models of care, which are not being considered in the current study. One example of this is the development of a service similar to cardiac services. In this model a physician, or medical angiologist, carries out the majority of diagnostic work-up and medical care and may also carry out interventional radiological procedures. The surgeon mainly provides a technical service for the physician. Such a model can be seen developing for PVD in some countries within Europe. At present, the speciality of medical angiology has not developed in the UK and this model has not been considered in the present study.

The possible scenarios for care that have been considered revolve around the extent to which the service is either centralised or devolved. Historically, vascular services were considered a part of general surgery and every hospital that provided a general surgical service would be expected to deal with patients with vascular disease. There has already been considerable sub-specialisation and there are no longer a full range of general surgical services provided at all hospitals. In terms of the provision of vascular services there are three main models of care that have been considered, but within this there are numerous possible variations.

A report on the provision of vascular services that was recently produced by the Vascular Surgical Society of Great Britain and Ireland[29] refers to the 'ideal' situation of a vascular unit serving a population of at least 500,000. This should be of sufficient size to justify an on-call arrangement and provide a full range of services. There are currently few units that serve a larger population and no available evidence to suggest advantages or disadvantages in further increasing the size of such units.

The operational modelling is based upon the available data and geographical arrangements in North Trent. The intention is, however, to make the modelling relevant to other areas in the UK.

Examination of the distribution of population of the districts in North Trent (*Table 1* and *Figure 1*) shows that there is sufficient population to support two or three such vascular centres. However, from the pragmatic viewpoint, considering geography, road links and the sizes of existing hospital stock, it seems likely that the only centre outside Sheffield that could reasonably become a second major vascular unit would be Doncaster. To provide the necessary catchment population Doncaster would need to take vascular referrals from Worksop and Rotherham, a total population of approximately 650,000.

For the purposes of modelling, all options that involve the centralisation of some or all vascular services will be considered for both a single-centre option, based in Sheffield and for a two-centre option with Doncaster serving the population of Rotherham, Worksop and Doncaster.

There are two components of changes in practice that may occur as a result of reorganisation of services. The first is a change in working practices. It can be seen from the workload analysis that there are several differences in the way that patients are managed, and the type of procedures carried out. Any reorganisation could be expected to have an immediate effect in this respect. The second component of change relates to differences in treatment rates. This may be subject to more gradual change following reorganisation as it may, at least in part, relate to referral practices.

For each model of organisation that has been considered there are a number of assumptions that must be made regarding the effect upon casemix and management, treatment rates, transfer policies and resource use. The scenarios are described in detail below and the major underlying assumptions are summarised in *Table 57*.

For all the changes the base case is taken as the situation that pertained for the 2-year period to which the data analysis applied. The rates and casemix for 'central' services are based upon those that were identified for Sheffield, with the 'local' rates being the average for all other North Trent hospitals. For the purposes of the two-centre model it is assumed that the second centre (Doncaster) would have management practices and outcomes similar to those identified as 'central'.

Devolved services

The current situation is that vascular services are largely devolved. Most hospitals with a general surgical service also offer vascular services with a few exceptions among the smallest hospitals. As noted in chapter 3 the major differences between centralised and devolved services relate to procedure rates and casemix. There may be mechanisms by which these could be altered to match those of the specialised centres through education and additional resources.

Three devolved models are tested. The first model (D1) assumes the current arrangements and rates of procedures but formalises the on-call rotas. Thus, emergency vascular admissions would be dealt with at the local hospital whenever a surgeon with a vascular specialist interest is available and would be transferred to the centre at other times.

The other devolved options assume a similar pattern but a change in workload and casemix for PVD to match the current central pattern (D2) and a similar increase for both PVD and carotid surgery (D3).

Centralised service

The second model of care is the fully centralised service in which all patients requiring vascular services are dealt with in a centre with sufficient sub-specialist staff to provide a full range of emergency and elective services. As discussed above both a single-centre and a two-centre option have been considered and for each there are three sub-options relating to the assumptions that are made with regard to rates and casemix. The first assumes the same overall rate for admissions, but with a change to the central casemix (C1), the second assumes central casemix and rates for PVD (C2) and the third assumes central rates for PVD and carotid surgery (C3).

Hub and spoke arrangements

It is already becoming clear that fully devolved services are not always possible due to constraints of manpower and resources. This has led to an informal arrangement with some services being provided at larger centres. The 'Hub and Spoke' model is a formalisation of this arrangement, whereby a clearly defined set of procedures and services are provided at both the major vascular centre (hub) and the smaller hospital (spoke). Although such arrangements are common at present, they are usually limited to the *ad hoc* transfer of emergency cases when an appropriate specialist is not available locally and the transfer of complex tertiary cases such as thoraco-abdominal aneurysm repairs. There are a variety of possibilities for producing formal arrangements for such a service.

- Both units may act independently but with formalised arrangements that define the categories of patients that will be transferred to the hub hospital.
- The service may be provided jointly by both hub and spoke hospitals, with some of the staff from the hub travelling to the spoke hospital to deliver a defined range of procedures and services (out-reach services).
- The hub hospital may provide the necessary support for clinicians from the spoke hospital to use specialist facilities for the treatment of some of their patients (in-reach service).

Within such arrangements there are a large number of different options covering the exact range of procedures or services that would be offered at either the hub or the spoke site. It may well be that it would be appropriate for different spoke hospitals to provide a different range of services, depending upon the size, local equipment and expertise.

From the point of view of resource usage there is probably little difference between the in-reach and out-reach options. There may, however, be implications in terms of issues such as training, recruitment and continuing medical education and these will be discussed below.

For the purposes of the modelling three possible hub and spoke arrangements have been considered. For each of them there are three sub-options with changes in rates of

***TABLE 57** Summary of main features and assumptions of options considered in modelling process*

Model	Description	Rates of procedures	Casemix assumptions	Transfers and local activity
D1	Present situation (based upon 2-year period for which data analysis was carried out)	Current rates for individual hospitals	Current casemix for individual hospitals	Formalise proportion of emergencies tranferred based on vascular cover in general rota or current local arrangements; supra-renal aortic and carotid groups treated centrally
D2	Devolved service but with the treatment of PVD and aortic matching current central practice	Increased rates to match the current central rates for PVD	Casemix for PVD as current central rates, aortic rates of operation as current central rates	As D1
D3	Devolved service but with the treatment of PVD and aortic matching current central practice and increased carotid referral rates to match current central rates	As D2 plus central rates for carotid surgery	As D2	As D2; carotids treated in central unit
C1	Fully centralised; one or two centralised units and residual practice at other centres matching non-vascular example; rates based on current local activity (i.e. level transfer from local to central)	Total rates of treatment remain constant. Rate of non-operated aortic admissions match central rates	Change in mix of PVD procedures and proportion of emergency aortic admissions treated match central rates	All inpatient and outpatient activity in central units apart from current levels for non-vascular hospital
C2	Fully centralised; one or two centralised units and residual practice at other centres matching non-vascular example with PVD rates increased to match current central practice	Total rates of PVD treatment match current central rates. Rate of non-operated aortic admissions match central rates	As C1	As C1
C3	Fully centralised; one or two centralised units and residual practice at other centres matching non-vascular example with PVD and carotid rates increased to match current central practice	Total rates of PVD and carotid treatment match current central rates. Rate of non-operated aortic admissions match central rates	As C1	As C1
HA1	Hub and spoke; one or two centralised units, residual practice at other centres matching non-vascular example but with outreach clinics and day-case facilities; rates based upon current local activity (i.e. level transfer from local to hub and spoke)	Total rates of treatment remain constant. Rate of non-operated aortic admissions match central rates	Change in mix of PVD procedures and proportion of emergency aortic admissions treated match central rates	All inpatient activity in central units; outpatient and elective day-case locally and other to match non-vascular rates
HA2	Hub and spoke; one or two centralised units, residual practice at other centres matching non-vascular example but with outreach clinics and day-case facilities with PVD rates increased to match current central practice	Total rates of PVD treatment match current central rates. Rate of non-operated aortic admissions match central rates	As HA1	As HA1

continued

TABLE 57 contd *Summary of main features and assumptions of options considered in modelling process*

Model	**Description**	**Rates of procedures**	**Casemix assumptions**	**Transfers and local activity**
HA3	Hub and spoke; one or two centralised units, residual practice at other centres matching non-vascular example but with outreach clinics and day-case facilities with PVD and carotid rates increased to match current central practice	Total rates of PVD and carotid treatment match current central rates. Rate of non-operated aortic admissions match central rates	As HA1	As HA1
HB1	Hub and spoke; one or two centralised units, residual practice at other centres includes outreach clinics, day-case facilities and elective diagnostic angiography; rates based upon current local activity (i.e. level transfer from local to hub and spoke)	As HA1	As HA1	All inpatient activity in central units – outpatient, elective day-case and elective diagnostic radiology locally and other to match non-vascular rates
HB2	Hub and spoke; one or two centralised units, residual practice at includes outreach clinics, day-case facilities and elective diagnostic angiography, with PVD rates increased to match current central practice	As HA2	As HA1	As HB1
HB3	Hub and spoke; one or two centralised units, residual practice at other centres matching non-vascular example but with outreach clinics, day-case facilities and elective diagnostic angiography, with PVD and carotid rates increased to match current central practice	As HA3	As HA1	As HB1
HC1	Hub and spoke; one or two centralised units, residual practice at other centres includes outreach clinics, day-case facilities, elective diagnostic angiography, interventional radiology and non-aortic PVD treatment; rates based upon current local activity (i.e. level transfer from local to hub and spoke)	As HA1	As HA1	All inpatient activity in central units; outpatient, elective day-case and elective diagnostic angiography, interventional radiology and non-aortic PVD treatment locally
HC2	Hub and spoke; one or two centralised units, residual practice at includes outreach clinics, day-case facilities, elective diagnostic angiography, interventional radiology and non-aortic PVD treatment, with PVD rates increased to match current central practice	As HA2	As HA1	As HC1
HC3	Hub and spoke; one or two centralised units, residual practice at other centres matching non-vascular example but with outreach clinics, day-case facilities, elective diagnostic angiography, interventional radiology and non-aortic PVD treatment, with PVD and carotid rates increased to match current central practice	As HA3	As HA1	As HC1

procedures and casemix corresponding to those described for the centralised models (C1–3). The first is based upon the Worksop arrangements, with no vascular radiology or surgery at the spoke hospital, but only outpatient and day-case facilities (HA1–3). The second is an intermediate arrangement with some facilities for elective diagnostic radiology at the spoke hospital (HB1–3) and the last is an arrangement with some elective interventional radiology, elective amputations and infra-inguinal vascular surgery being carried out in the spoke hospital (HC1–3).

Predictive model for resource use

Modelling has been used in order to quantify the likely resource implications of the reconfiguration of vascular services. The model has been designed using an Excel spreadsheet with consideration of each of the casemix categories described above. There are a number of stages in the modelling process.

- The various data inputs required have been obtained from the evaluation of workload in the North Trent area.
- Estimates of likely resource use have been obtained as described in chapter 6.
- This has been used to design a base case model based on current working practices and resource use and the outputs from this model have been compared with what is known of current resource usage in order to assess its accuracy.
- A set of options has been defined that describe ways in which the vascular services for North Trent could be reconfigured.
- The casemix categories have been considered individually in order to predict the likely changes that take place under each of the different scenarios.
- These changes have then been modelled in the spreadsheet and estimations made of the total resource implications of the resulting changes in workload and practice.
- Consideration has been given to the likely affect of reconfiguration of services on outcomes based on the review in chapters 4 and 5.
- The costs described in chapter 6 (*Resource use*) have been used to estimate some of the costs of the reconfiguration of service.
- Sensitivity analysis has been carried out to consider some of the known causes of potential inaccuracy and to test some of the key assumptions.

Data definitions and assumptions

Casemix categories

The casemix categories used for the analysis are those defined previously and detailed in appendix 1.

All the peripheral vascular and amputation groups are split into emergency and routine subgroups for consideration in the model. These have very different resource implications and the mode of admission may affect the site to which they would be admitted under some of the options for configuration of services. The category for major amputation has excluded the orthopaedic cases and an attempt has been made to exclude the cardiology procedures from the angiography category by excluding cases where the primary diagnosis is clearly cardiac or there is a procedural code for a cardiac procedure.

The casemix category covering supra-renal aortic and visceral artery surgery is small and has been kept as a single category covering both elective and emergency admissions. In all options it has been assumed that this group would be treated in the central unit. Carotid surgery has not been split into emergency and elective, as there are very small numbers of emergency admissions.

It must be noted that the categories are defined based on the hierarchy of procedures given in appendix 1. As a result of this some of the patients undergoing the more major procedures, for example major amputation, will have also undergone other procedures such as vascular reconstruction or angioplasty as discussed in chapter 3 (*Secondary procedures*). This has been taken into consideration in calculating the resource use of such procedures.

Population rates

The rates for particular procedures and casemix categories are based upon the current study using the 1995–97 data for the Trent region.

The estimates of population are based on the projected figures for mid-1996 from the OPCS.[11]

The Worksop catchment area is estimated to be 105,000. As separate rates of procedures were not available for this population the rates have been based on the average for North Nottinghamshire.

Transfers

One of the inputs into the model is the proportion of patients in particular districts that are dealt with by Sheffield. For some district and casemix categories there are already substantial numbers of patients transferred to Sheffield. In the base case analysis the current referral practices have been assumed to continue at their present level. The likely changes in referral have been modelled for each of the possible configuration of service.

Flows of patients across boundaries between other districts in Trent have been ignored. These are of very small numbers and occur in both directions, so are unlikely to make significant differences to the overall estimates.

Differences in treatment

Within some casemix categories there may be differences between centres in patient management, and where this is likely to be affected by reconfiguration of services the figures have been included as an input to the model. This includes the proportion of emergency aortic admissions in which there is vascular surgery, the rate of elective aortic admissions, in which there is no procedure (i.e. admissions for investigation and assessment only), and the distribution of PVD patients between different treatments such as angioplasty, reconstruction and amputation.

Resource use

Details of the methods used for analysing resource use are given in chapter 6. The following resource use parameters have been included as inputs to the model.

- Length of stay has been taken from the data specific to individual hospitals (*Table 50*). This is based on means of untrimmed data giving a total number of bed-days. Total bed requirements would need to be corrected for bed occupancy and where estimates of length of stay are based upon fewer that five cases the average for North Trent has been used.
- Theatre usage has been estimated using data available at the NGH in Sheffield and from Huddersfield and corrected to allow for secondary procedures during the same episode (*Table 49*). Other centres were not able to supply data in sufficient detail to be used. The total theatre times are presented and the total number of sessions required calculated based on a session of 210 minutes. The total number of sessions required has been calculated based on 77%, which is the current usage of vascular surgical scheduled theatre time in Sheffield. It is impossible from the available data to adequately separate the requirements for emergency and elective theatre time. This is because many vascular procedures are semi-urgent and may, therefore, be included on the next scheduled list or dealt with in emergency theatre time, depending on the availability of these resources and local practices. An assessment of theatre data in Sheffield has revealed that approximately 25% of vascular operating time is unscheduled, though only about 10% are true emergencies (urgent aneurysms or acute ischaemia). The remainder could be carried out on scheduled lists if these were available at short notice.
- Outpatient visits have been estimated based upon the policies described by individual consultants when interviewed. For those cases where there is no information available, these figures have been estimated (*Table 53*).
- Radiology procedures have been estimated from specific discussion with the radiology departments, evidence of working practices as gained from consultant interviews, and the analysis of the database. Many of the casemix groups include angiography as a secondary procedure, and *Table 52* gives the number of procedures that have been allocated to each of the casemix categories.
- ITU/HDU usage have been estimated from the ITU and HDU information system at the NGH and the resulting number of ITU/HDU bed-days allocated to each of the casemix categories are given in *Table 51*. The availability and practices relating to ITU and HDU beds varies from district to district, these facilities have been considered as a whole.

For the purposes of the model it has been assumed that, where there is a shift in workload, the estimate of resources used is based upon data from the hospital in which the work is carried out. The evidence from the literature review suggests that the majority of variation in resource use relates to working practices and outcome. However, there may also be an effect due to casemix selection and this has been addressed in the discussion.

Scenarios for casemix groupings

Under each scenario there are a number of factors that may need to be considered for each casemix group.

- The rate of admissions for that casemix group within the particular population may change as a result of the configuration of services.

- Within the casemix group there may be differences in the types of procedures carried out.
- The proportion of patients that are treated at the local hospital or the centralised unit may vary.
- The resource use may alter due to differences in workload or in working practices.

Each of the casemix groups is considered below in respect of the likely changes that would be expected under each of the scenarios described above.

Emergency aortic admissions

It seems unlikely that reconfiguration of services would affect the overall rate of admissions in this category. However, the proportion transferred to the central unit would alter under the different configurations and the proportion undergoing surgery may also alter due to differences in policy. These changes would also be likely to have knock-on effects for resource usage.

For the devolved models emergency aortic surgery was assumed to be carried out at the local hospital in proportion to the time that a consultant with a vascular interest was available on the on-call rota for that hospital. The rates of procedures remained unchanged and working practices were considered unchanged for model D1, but matched those of the centre for options D2 and D3.

In all centralised and hub and spoke arrangements emergency aortic cases were assumed to be treated at the central hospital with working practices matching central rates. In hub and spoke arrangements it is assumed that follow-up will be carried out locally.

Elective aortic admissions

The reconfiguration of services may affect a number of aspects of elective aortic admissions. The population rates for the procedures may be altered due to differences in policy regarding the selection of patients, there may be a change in the proportion of patients who have an admission without operation for assessment and investigation, and differences in workload and practice may affect the total resource use.

For the devolved models all elective aortic surgery was assumed to be carried out at the local hospital. The rates of procedures remained unchanged and working practices were considered unchanged for model D1, but matched those of the centre for options D2 and D3.

In all centralised and hub and spoke arrangements elective aortic cases were assumed to be treated at the central hospital with working practices matching central rates. In hub and spoke arrangements it is assumed that initial outpatient assessment and follow-up will be carried out locally.

Carotid surgery

Most carotid surgery is already carried out in the central unit so a major effect on the rates of transfer or the resource use for individual procedures is unlikely. However, it may be that different configurations would affect the number of referrals and hence the population rates of the procedure. The evidence presented in chapter 4 (*Carotid endarterectomy*) suggests that there is current under-provision of carotid surgery in many districts and this issue will be considered separately below.

In all models it is assumed that carotid surgery will continue to be carried out at the central unit. In models D1–2, C1–2, HA1–2, HB1–2 and HC1–2 it is assumed that the overall rate is unchanged. Models D3, C3, HA3, HB3 and HC3 assume an increase in carotid surgery to match central rates.

In hub and spoke arrangements it is assumed that initial outpatient assessment and follow-up will be carried out locally.

Upper limb vascular surgery

This represents a small group of patients, most of whom are emergency admissions and the majority of whom are under embolectomy. It is unlikely that changes of configuration would make major differences to the referral rates or resource use of individual patients. For the devolved models it is assumed that emergencies will be admitted as with emergency aortic cases. All centralised and hub and spoke models assume central treatment with local follow-up in the latter.

Emergency PVD/major amputation

These categories have been treated as a whole to allow consideration of the variation in the mix of procedures. Under the different arrangement it is likely that the rates of admission for particular procedures would vary due to differences in practice. There are likely to be changes in the mix of procedures and within each procedure there may be differences in working practice, such as the use of prosthetic or vein grafts and the level of amputation. Such changes may lead to differences in resource use.

In the devolved arrangement these would be carried out locally in proportion to the available vascular specialists, as with emergency aortic surgery, with current rates in option D1 and central rates in D2–3. In all centralised and hub and spoke arrangements they would be carried out at the centre, with current rates and central casemix in options C1, HA1, HB1 and HC1 and central rates and casemix in the other options.

Elective PVD

The expected differences are similar to those described above for emergency PVD. There are, however, issues about the nature of procedures that would be carried out in the spoke hospital.

In the devolved arrangement these procedures would be carried out locally with current rates in option D1 and central rates in D2–3. In all centralised and the first hub and spoke arrangements they would be carried out with central casemix, with admission rates matching current levels in options C1, HA1, HB1 and HC1 and central rates in the other options. The centralised option and HA assume central treatment with local follow-up in the latter. HB options assume that elective diagnostic radiology will also be carried out locally, and HC options include local treatment for elective amputation and infra-inguinal surgery.

Varicose veins

Under all arrangements varicose veins would be carried out locally, though there is a small proportion of complex or recurrent cases that may be referred to a vascular specialist. The importance of estimating the workload relating to varicose veins is that under a hub and spoke arrangement they may constitute part of the workload cared for by the vascular specialist at the spoke hospital.

Results of model

The results of the modelling are presented first for the base-case model. The number of episodes in each hospital is then considered for each of the options and sub-options. The resource parameters are then considered separately, followed by a consideration of outcomes and costs.

Base case

Table 58 shows the results of the base case for FCEs by casemix groups and hospital.

TABLE 58 *Base case – estimated number of FCEs per year for each of the casemix groups in each centre*

	Barnsley	Doncaster	North Derbyshire	Worksop	Rotherham	Sheffield
Supra-renal AAA	3	1	3	0	0	9
Aortic – elective	15	23	32	0	10	60
Aortic – emergency	10	17	21	0	15	56
Carotid	0	2	1	0	0	91
Upper limb	6	1	6	0	1	15
Major amputation – emergency	22	34	38	6	20	62
Femoro-distal – emergency	1	1	2	0	0	11
Reconstruction – emergency	12	20	26	0	10	95
Minor amputation – emergency	3	15	5	3	6	37
Angioplasty – emergency	2	22	13	0	9	58
Angiography – emergency	9	22	21	0	18	94
Major amputation – elective	9	12	17	2	4	31
Femoro-distal – elective	2	2	2	0	0	9
Reconstruction – elective	22	33	29	0	21	95
Minor amputation – elective	3	9	6	0	7	26
Angioplasty – elective	32	107	66	0	62	278
Angiography – elective	78	116	100	0	130	512
Varicose veins	245	449	351	115	318	715
Total	**474**	**882**	**739**	**125**	**629**	**2253**

TABLE 59 *Base case – estimated use of resources per year for each of the centres in North Trent*

	Barnsley	Doncaster	North Derbyshire	Worksop	Rotherham	Sheffield	Total
Bed-days	2660	4063	4743	301	2795	14,658	29,220
Theatre time	32,569	51,511	52,031	7640	31,324	148,571	323,647
X-ray procedures	181	374	301	4	287	1307	2453
ITU/HDU bed-days	91	134	173	6	69	598	1072
Outpatient visits	1240	2267	1989	259	1549	6246	13,550
Maximum costs (£1000s)	1011	1604	1751	135	1062	5544	11,107
Minimum costs (£1000s)	879	1401	1525	114	933	4862	9713
Beds	7.67	11.72	13.68	0.87	8.06	42.27	84.27
Theatre sessions	202	319	322	47	194	920	2005

The results of this model suggest a total of 2253 episodes relating to vascular services in Sheffield. This corresponds reasonably well with the known activity of the Sheffield Vascular Unit, although, as discussed in chapter 6 there are significant differences between the definitions used and methods for identifying data, which are likely to explain the discrepancies. Since the main intention of the modelling is to consider comparative data to predict the effect of reconfiguration, these small differences are unlikely to be significant.

Table 59 shows the estimates of resources used in terms of bed-days, theatre minutes, radiology procedures, ITU/HDU bed-days and outpatient visits. These are used to calculate total estimated costs for which minimum and maximum estimates are given based upon the estimates in chapter 6 (*Resource use*). Finally the number of ward beds and operating sessions are estimated based upon the estimated bed occupancy and usage of operating theatre time.

It is important to note that, as discussed in chapter 6, although the estimates for length of stay and numbers of admissions are based upon data from the districts concerned, the more detailed data are based on a limited subset of providers, particularly from Sheffield. Thus, the estimates for Sheffield are likely to be more accurate than those for other centres in respect of theatre time, ITU usage and costs.

Table 60 provides estimates of certain key parameters that were identified as possible indicators of outcome, such as number of aneurysms treated centrally, amputations, angioplasties and carotid operations for the whole of North Trent.

TABLE 60 *Base case – estimated key outcome parameters per year for the whole of North Trent*

Outcome	*n*
Centralised elective AAA	60
Centralised emergency AAA	56
Major amputation	273
Below-knee amputation	98
Total femoral-popliteal distal	226
Prosthetic graft	123
Angioplasty	648
CE	94

Each of the figures in *Tables 58* to *60* were recalculated for each of the model options described above (as summarised in *Table 57*) and the results are summarised below.

The number of FCEs that would be expected in each centre are given in *Table 61* for each of the models considered. It can be seen that there are three levels of overall activity modelled, based upon current activity or increased activity to meet the central rates for PVD or PVD and carotid surgery. The latter give overall increases on 442 and 484 episodes per year, respectively. There is considerable variation in the distribution of this workload depending upon the

TABLE 61 *Total number of expected FCEs per year (and change from base case) for each of the options considered in the model*

	Sheffield	Doncaster	Barnsley	North Derbyshire	Worksop	Rotherham	Net
Base case	2253 (0)	882 (0)	474 (0)	739 (0)	125 (0)	629 (0)	0
Single-centre models							
D1	2042 (–211)	937 (54)	531 (56)	787 (48)	125 (0)	681 (52)	0
D2	2292 (40)	988 (106)	573 (99)	898 (159)	122 (–2)	671 (41)	442
D3	2333 (80)	989 (107)	573 (99)	898 (159)	122 (–2)	671 (41)	484
C1	3547 (1294)	471 (–411)	257 (–217)	372 (–367)	122 (–3)	333 (–296)	0
C2	3974 (1721)	470 (–412)	262 (–212)	379 (–360)	122 (–2)	337 (–292)	442
C3	4015 (1763)	470 (–412)	262 (–212)	379 (–360)	122 (–2)	337 (–292)	484
HA1	3547 (1294)	471 (–411)	257 (–217)	372 (–367)	122 (–3)	333 (–296)	0
HA2	3974 (1721)	470 (–412)	262 (–212)	379 (–360)	122 (–2)	337 (–292)	442
HA3	4015 (1763)	470 (–412)	262 (–212)	379 (–360)	122 (–2)	337 (–292)	484
HB1	2888 (635)	639 (–243)	386 (–89)	546 (–193)	124 (–1)	520 (–110)	0
HB2	3072 (819)	700 (–182)	438 (–36)	673 (–66)	125 (0)	537 (–93)	442
HB3	3114 (861)	700 (–182)	438 (–36)	673 (–66)	125 (0)	537 (–93)	484
HC1	2404 (152)	794 (–88)	470 (–5)	687 (–52)	122 (–3)	625 (–4)	0
HC2	2492 (239)	849 (–33)	552 (78)	863 (124)	122 (–2)	666 (37)	442
HC3	2533 (281)	849 (–33)	552 (78)	863 (124)	122 (–2)	666 (37)	484
Two-centre models							
C1	2486 (233)	1532 (650)	257 (–217)	372 (–367)	122 (–3)	333 (–296)	0
C2	2765 (512)	1680 (797)	262 (–212)	379 (–360)	122 (–2)	337 (–292)	442
C3	2788 (536)	1698 (815)	262 (–212)	379 (–360)	122 (–2)	337 (–292)	484
HA1	2486 (233)	1532 (650)	257 (–217)	372 (–367)	122 (–3)	333 (–296)	0
HA2	2765 (512)	1680 (797)	262 (–212)	379 (–360)	122 (–2)	337 (–292)	442
HA3	2788 (536)	1698 (815)	262 (–212)	379 (–360)	122 (–2)	337 (–292)	484
HB1	2183 (–69)	1343 (461)	386 (–89)	546 (–193)	124 (–1)	520 (–110)	0
HB2	2295 (42)	1477 (595)	438 (–36)	673 (–66)	125 (0)	537 (–93)	442
HB3	2319 (66)	1495 (613)	438 (–36)	673 (–66)	125 (0)	537 (–93)	484
HC1	1958 (–294)	1240 (358)	470 (–5)	687 (–52)	122 (–3)	625 (–4)	0
HC2	1990 (–262)	1351 (468)	552 (78)	863 (124)	122 (–2)	666 (37)	442
HC3	2014 (–239)	1368 (486)	552 (78)	863 (124)	122 (–2)	666 (37)	484

model adopted. The maximum shift in activity (one-centre model C3 and HA3) would require an additional 1763 episodes per year in Sheffield, while some of the devolved and two-centre models would result in an overall shift in activity away from Sheffield.

Table 62 shows similar figures for the estimated total number of bed-days per year that would be required under each of the options, showing a maximum total increase in bed-days of 4190 for all of North Trent.

Similarly, the expected time in theatre, number of radiological procedures, required ITU and HDU beds and number of out-patient visits are shown in *Tables 63* to *67*. In the case of HDU/ITU beds it should be noted that not all hospitals provide both facilities at present, but those that are limited to a single unit have a mixed caseload and

TABLE 62 *Total number of expected bed-days required per year (and change from base case) for each of the options considered in the model*

	Sheffield	Doncaster	Barnsley	North Derbyshire	Worksop	Rotherham	Net
Base case	14,658 (0)	4063 (0)	2660 (0)	4743 (0)	301 (0)	2795 (0)	0
Single-centre models							
D1	14,008 (–650)	4492 (429)	2775 (115)	4605 (–138)	301 (0)	2899 (104)	–140
D2	17,840 (3182)	4770 (707)	2436 (–224)	4147 (–595)	247 (–54)	2530 (–264)	2785
D3	18,172 (3514)	4776 (713)	2436 (–224)	4147 (–595)	247 (–54)	2530 (–264)	3124
C1	26,254 (11,596)	879 (–3,184)	592 (–2067)	1013 (–3729)	233 (–69)	741 (–2054)	492
C2	29,196 (14,539)	861 (–3202)	710 (–1950)	1209 (–3534)	247 (–54)	847 (–1948)	3852
C3	29,535 (14,877)	861 (–3202)	710 (–1950)	1209 (–3534)	247 (–54)	847 (–1948)	4190
HA1	26,254 (11,596)	879 (–3184)	592 (–2067)	1013 (–3729)	233 (–69)	741 (–2054)	492
HA2	29,196 (14,539)	861 (–3202)	710 (–1950)	1209 (–3534)	247 (–54)	847 (–1948)	3852
HA3	29,535 (14,877)	861 (–3202)	710 (–1950)	1209 (–3534)	247 (–54)	847 (–1948)	4190
HB1	23,849 (9191)	1427 (–2636)	1010 (–1650)	1749 (–2994)	237 (–64)	1210 (–1584)	263
HB2	25,705 (11,047)	1619 (–2444)	1395 (–1265)	2432 (–2311)	252 (–49)	1394 (–1400)	3578
HB3	26,044 (11,386)	1619 (–2444)	1395 (–1265)	2432 (–2311)	252 (–49)	1394 (–1400)	3917
HC1	20,164 (5506)	2244 (–1819)	1599 (–1061)	2677 (–2066)	233 (–69)	1974 (–821)	–329
HC2	21,280 (6622)	2403 (–1660)	2196 (–463)	3684 (–1059)	247 (–54)	2333 (–462)	2923
HC3	21,619 (6961)	2403 (–1660)	2196 (–463)	3684 (–1059)	247 (–54)	2333 (–462)	3262
Two-centre models							
C1	16,937 (2279)	10,196 (6133)	592 (–2067)	1013 (–3729)	233 (–69)	741 (–2054)	492
C2	19,060 (4402)	10,998 (6935)	710 (–1950)	1209 (–3534)	247 (–54)	847 (–1948)	3852
C3	19,253 (4595)	11,144 (7081)	710 (–1950)	1209 (–3534)	247 (–54)	847 (–1948)	4190
HA1	16,937 (2279)	10,196 (6133)	592 (–2067)	1013 (–3729)	233 (–69)	741 (–2054)	492
HA2	19,060 (4402)	10,998 (6935)	710 (–1950)	1209 (–3534)	247 (–54)	847 (–1948)	3852
HA3	19,253 (4595)	11,144 (7081)	710 (–1950)	1209 (–3534)	247 (–54)	847 (–1948)	4190
HB1	15,853 (1195)	9423 (5360)	1010 (–1650)	1749 (–2994)	237 (–64)	1210 (–1584)	263
HB2	17,247 (2589)	10,078 (6015)	1395 (–1265)	2432 (–2311)	252 (–49)	1394 (–1400)	3578
HB3	17,440 (2782)	10,223 (6160)	1395 (–1265)	2432 (–2311)	252 (–49)	1394 (–1400)	3917
HC1	14,138 (–520)	8271 (4208)	1599 (–1061)	2677 (–2066)	233 (–69)	1974 (–821)	–329
HC2	14,925 (267)	8758 (4695)	2196 (–463)	3684 (–1059)	247 (–54)	2333 (–462)	2923
HC3	15,118 (460)	8904 (4841)	2196 (–463)	3684 (–1059)	247 (–54)	2333 (–462)	3262

the figures provide estimates of the degree of dependency required.

Implications for outcomes and cost

Outcome

For each of the options for the configuration of services the possible effect on outcomes has been considered. It has been assumed that the effect upon outcomes of a centralised service will be similar irrespective of the site at which that centralised service is provided.

A comparison has been made with the base case in order to determine the changes in particular parameters that are likely to affect outcome. As discussed in chapters 4 and 5, there are a number of areas in which specific issues have been identified that may have an effect on outcome, including:

TABLE 63 Total number of expected theatre hours required per year (and change from base case) for each of the options considered in the model

	Sheffield	Doncaster	Barnsley	North Derbyshire	Worksop	Rotherham	Net
Base case	148,571 (0)	51,511 (0)	32,569 (0)	52,031 (0)	7640 (0)	31,324 (0)	0
Single-centre models							
D1	145,171 (–3400)	54,345 (2834)	33,013 (444)	50,451 (–1580)	7640 (0)	32,817 (1492)	–210
D2	164,405 (15,834)	55,948 (4437)	28,677 (–3892)	45,401 (–6630)	7208 (–432)	32,690 (1366)	8806
D3	170,607 (22,036)	56,063 (4552)	28,677 (–3892)	45,401 (–6630)	7208 (–432)	32,690 (1366)	15,123
C1	244,661 (96,090)	27,242 (–24,269)	14,868 (–17,701)	21,694 (–30,337)	7114 (–526)	19,220 (–12,105)	11,151
C2	249,681 (101,110)	27,125 (–24,387)	15,437 (–17,132)	22,618 (–29,413)	7208 (–432)	19,672 (–11,653)	18,095
C3	255,998 (107,427)	27,125 (–24,387)	15,437 (–17,132)	22,618 (–29,413)	7208 (–432)	19,672 (–11,653)	24,412
HA1	244,661 (96,090)	27,242 (–24,269)	14,868 (–17,701)	21,694 (–30,337)	7114 (–526)	19,220 (–12,105)	11,151
HA2	249,681 (101,110)	27,125 (–24,387)	15,437 (–17,132)	22,618 (–29,413)	7208 (–432)	19,672 (–11,653)	18,095
HA3	255,998 (107,427)	27,125 (–24,387)	15,437 (–17,132)	22,618 (–29,413)	7208 (–432)	19,672 (–11,653)	24,412
HB1	243,256 (94,685)	27,651 (–23,860)	15,089 (–17,480)	22,065 (–29,966)	7240 (–400)	19,497 (–11,827)	11,151
HB2	248,007 (99,436)	27,517 (–23,994)	15,738 (–16,831)	23,119 (–28,912)	7348 (–292)	20,013 (–11,312)	18,095
HB3	254,324 (105,753)	27,517 (–23,994)	15,738 (–16,831)	23,119 (–28,912)	7348 (–292)	20,013 (–11,312)	24,412
HC1	212,525 (63,954)	37,516 (–13,995)	20,418 (–12,152)	31,031 (–21,001)	7114 (–526)	26,194 (–5130)	11,151
HC2	211,104 (62,533)	36,986 (–14,526)	22,993 (–9576)	35,212 (–16,819)	7208 (–432)	28,238 (–3086)	18,095
HC3	217,421 (68,850)	36,986 (–14,526)	22,993 (–9576)	35,212 (–16,819)	7208 (–432)	28,238 (–3086)	24,412
Two-centre models							
C1	167,808 (19,237)	104,095 (52,583)	14,868 (–17,701)	21,694 (–30,337)	7114 (–526)	19,220 (–12,105)	11,151
C2	173,601 (25,030)	103,205 (51,694)	15,437 (–17,132)	22,618 (–29,413)	7208 (–432)	19,672 (–11,653)	18,095
C3	177,207 (28,636)	105,916 (54,405)	15,437 (–17,132)	22,618 (–29,413)	7208 (–432)	19,672 (–11,653)	24,412
HA1	167,808 (19,237)	104,095 (52,583)	14,868 (–17,701)	21,694 (–30,337)	7114 (–526)	19,220 (–12,105)	11,151
HA2	173,601 (25,030)	103,205 (51,694)	15,437 (–17,132)	22,618 (–29,413)	7208 (–432)	19,672 (–11,653)	18,095
HA3	177,207 (28,636)	105,916 (54,405)	15,437 (–17,132)	22,618 (–29,413)	7208 (–432)	19,672 (–11,653)	24,412
HB1	167,216 (18,645)	103,691 (52,180)	15,089 (–17,480)	22,065 (–29,966)	7240 (–400)	19,497 (–11,827)	11,151
HB2	172,799 (24,228)	102,725 (51,213)	15,738 (–16,831)	23,119 (–28,912)	7348 (–292)	20,013 (–11,312)	18,095
HB3	176,405 (27,834)	105,435 (53,924)	15,738 (–16,831)	23,119 (–28,912)	7348 (–292)	20,013 (–11,312)	24,412
HC1	152,921 (4350)	97,120 (45,609)	20,418 (–12,152)	31,031 (–21,001)	7114 (–526)	26,194 (–5130)	11,151
HC2	153,451 (4880)	94,638 (43,127)	22,993 (–9576)	35,212 (–16,819)	7208 (–432)	28,238 (–3086)	18,095
HC3	157,058 (8487)	97,349 (45,838)	22,993 (–9576)	35,212 (–16,819)	7208 (–432)	28,238 (–3086)	24,412

- those areas in which there is evidence of difference in outcomes related to the volume of procedures carried out, in particular elective and emergency aortic surgery. The evidence of the review in chapter 4, (*The relationship between volume and outcome*) and the report of the Vascular Surgical Society[29] suggest that transfers between hospitals involving the distances within North Trent (< 1 hour transfer time) do not have significant effect on overall mortality from emergency aortic surgery.)
- the total number of amputations carried out
- the proportion of major amputations likely to be carried out at the below-knee level
- the number of patients treated by angioplasty
- the proportion of patients undergoing femoro-popliteal bypasses who have a vein graft, rather than prosthetic material
- the rate of CE.

Although it is clear that there may be ways of influencing these outcomes other than through

TABLE 64 *Total number of expected vascular radiological procedures required per year (and change from base case) for each of the options considered in the model*

	Sheffield	Doncaster	Barnsley	North Derbyshire	Worksop	Rotherham	Net
Base case	1307 (0)	374 (0)	181 (0)	301 (0)	0 (0)	287 (0)	0
Single-centre models							
D1	1068 (–239)	425 (51)	245 (65)	362 (61)	0 (0)	352 (65)	–1
D2	1308 (1)	490 (116)	317 (136)	514 (212)	0 (0)	349 (62)	–22
D3	1310 (3)	490 (116)	317 (136)	514 (212)	0 (0)	349 (62)	10
C1	2440 (1133)	0 (–374)	0 (–181)	0 (–301)	0 (0)	0 (–287)	30
C2	2940 (1633)	0 (–374)	0 (–181)	0 (–301)	0 (0)	0 (–287)	13
C3	2943 (1636)	0 (–374)	0 (–181)	0 (–301)	0 (0)	0 (–287)	46
HA1	2440 (1133)	0 (–374)	0 (–181)	0 (–301)	0 (0)	0 (–287)	30
HA2	2940 (1633)	0 (–374)	0 (–181)	0 (–301)	0 (0)	0 (–287)	13
HA3	2943 (1636)	0 (–374)	0 (–181)	0 (–301)	0 (0)	0 (–287)	46
HB1	1699 (392)	196 (–178)	160 (–21)	204 (–97)	0 (0)	216 (–71)	30
HB2	1915 (608)	269 (–105)	219 (38)	344 (42)	0 (0)	234 (–53)	13
HB3	1918 (611)	269 (–105)	219 (38)	344 (42)	0 (0)	234 (–53)	46
HC1	1249 (–58)	340 (–34)	230 (49)	335 (34)	0 (0)	314 (27)	30
HC2	1375 (68)	407 (33)	314 (134)	520 (219)	0 (0)	354 (67)	13
HC3	1377 (71)	407 (33)	314 (134)	520 (219)	0 (0)	354 (67)	46
Two-centre models							
C1	1550 (243)	897 (523)	0 (–181)	0 (–301)	0 (0)	0 (–287)	30
C2	1865 (558)	1083 (709)	0 (–181)	0 (–301)	0 (0)	0 (–287)	13
C3	1866 (559)	1084 (710)	0 (–181)	0 (–301)	0 (0)	0 (–287)	46
HA1	1550 (243)	897 (523)	0 (–181)	0 (–301)	0 (0)	0 (–287)	30
HA2	1865 (558)	1083 (709)	0 (–181)	0 (–301)	0 (0)	0 (–287)	13
HA3	1866 (559)	1084 (710)	0 (–181)	0 (–301)	0 (0)	0 (–287)	46
HB1	1209 (–98)	685 (312)	160 (–21)	204 (–97)	0 (0)	216 (–71)	30
HB2	1330 (23)	855 (481)	219 (38)	344 (42)	0 (0)	234 (–53)	13
HB3	1331 (24)	856 (482)	219 (38)	344 (42)	0 (0)	234 (–53)	46
HC1	1001 (–306)	588 (214)	230 (49)	335 (34)	0 (0)	314 (27)	30
HC2	1047 (–260)	735 (361)	314 (134)	520 (219)	0 (0)	354 (67)	13
HC3	1049 (–258)	736 (362)	314 (134)	520 (219)	0 (0)	354 (67)	46

the reconfiguration of services, the differences would appear, from the literature reviewed, to be commonly associated with organisational structure. There is also no evidence upon which to base an analysis of the effectiveness or cost-effectiveness of other possible strategies.

Costs

Chapter 6 (*Resource use*) of this report detailed the methods used for costing of procedures for the purposes of this report. The cost estimates for each casemix group are summarised in *Table 56*. There are some limitations to the costing, as it has been necessary to concentrate on the detailed data that were available in Sheffield. For this reason the results have primarily been reported as disaggregated figures for resource use, as presented in *Tables 61* to *67*. Such data are also much more useful when planning a reconfiguration of the service.

Tables 68 and *69* give the estimated maximum and minimum total costs for each centre for the

TABLE 65 *Total number of ITU beds required per year (and change from base case) for each of the options considered in the model*

	Sheffield	Doncaster	Barnsley	North Derbyshire	Worksop	Rotherham	Net
Base case	382 (0)	92 (0)	64 (0)	120 (0)	5 (0)	49 (0)	0
Single-centre models							
D1	405 (22)	99 (6)	55 (–9)	107 (–13)	5 (0)	52 (3)	9
D2	453 (71)	86 (–6)	36 (–28)	66 (–54)	3 (–2)	34 (–15)	–69
D3	457 (75)	86 (–6)	36 (–28)	66 (–54)	3 (–2)	34 (–15)	–65
C1	764 (381)	10 (–83)	5 (–59)	9 (–111)	3 (–2)	7 (–43)	83
C2	723 (340)	9 (–83)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	49
C3	726 (344)	9 (–83)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	52
HA1	764 (381)	10 (–83)	5 (–59)	9 (–111)	3 (–2)	7 (–43)	83
HA2	723 (340)	9 (–83)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	49
HA3	726 (344)	9 (–83)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	52
HB1	764 (381)	10 (–83)	5 (–59)	9 (–111)	3 (–2)	7 (–43)	83
HB2	723 (340)	9 (–83)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	49
HB3	726 (344)	9 (–83)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	52
HC1	729 (346)	21 (–72)	11 (–53)	19 (–101)	3 (–2)	14 (–35)	83
HC2	681 (298)	20 (–72)	15 (–49)	25 (–95)	3 (–2)	17 (–32)	49
HC3	684 (302)	20 (–72)	15 (–49)	25 (–95)	3 (–2)	17 (–32)	52
Two-centre models							
C1	474 (92)	299 (207)	5 (–59)	9 (–111)	3 (–2)	7 (–43)	83
C2	467 (85)	265 (172)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	49
C3	470 (87)	266 (174)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	52
HA1	474 (92)	299 (207)	5 (–59)	9 (–111)	3 (–2)	7 (–43)	83
HA2	467 (85)	265 (172)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	49
HA3	470 (87)	266 (174)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	52
HB1	474 (92)	299 (207)	5 (–59)	9 (–111)	3 (–2)	7 (–43)	83
HB2	467 (85)	265 (172)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	49
HB3	470 (87)	266 (174)	7 (–57)	12 (–108)	3 (–2)	8 (–41)	52
HC1	458 (76)	291 (199)	11 (–53)	19 (–101)	3 (–2)	14 (–35)	83
HC2	445 (63)	255 (163)	15 (–49)	25 (–95)	3 (–2)	17 (–32)	49
HC3	448 (65)	257 (164)	15 (–49)	25 (–95)	3 (–2)	17 (–32)	52

different models considered. They demonstrate a number of points. These are clearly estimates based upon average figures and there are a number of issues that need to be taken into account when costing the reconfiguration of services. Most of these issues would need to be addressed locally with the individual units in which there would be a change in activity.

- The main problem that many units would face is that certain resources are difficult to release, despite a reduction in workload. This is particularly true of the release of key members of personnel or where fractions of a full-time equivalent of particular staff are involved.
- The removal of one member of staff, particularly consultant staff, may leave problems with the residual service due to rota arrangements or other commitments.
- It may be difficult to release beds due to the practicalities of nursing particular

***TABLE 66** Total number of HDU beds required per year (and change from base case) for each of the options considered in the model*

	Sheffield	Doncaster	Barnsley	North Derbyshire	Worksop	Rotherham	Net
Base case	216 (0)	42 (0)	26 (0)	53 (0)	1 (0)	20 (0)	0
Single-centre models							
D1	196 (–20)	46 (5)	31 (5)	57 (4)	1 (0)	26 (6)	–1
D2	209 (–7)	42 (0)	24 (–2)	44 (–9)	1 (0)	22 (2)	–22
D3	242 (26)	42 (1)	24 (–2)	44 (–9)	1 (0)	22 (2)	10
C1	381 (165)	2 (–40)	1 (–25)	2 (–51)	1 (–1)	1 (–19)	30
C2	363 (147)	2 (–40)	2 (–25)	3 (–51)	1 (0)	2 (–18)	13
C3	396 (180)	2 (–40)	2 (–25)	3 (–51)	1 (0)	2 (–18)	46
HA1	381 (165)	2 (–40)	1 (–25)	2 (–51)	1 (–1)	1 (–19)	30
HA2	363 (147)	2 (–40)	2 (–25)	3 (–51)	1 (0)	2 (–18)	13
HA3	396 (180)	2 (–40)	2 (–25)	3 (–51)	1 (0)	2 (–18)	46
HB1	381 (165)	2 (–40)	1 (–25)	2 (–51)	1 (–1)	1 (–19)	30
HB2	363 (147)	2 (–40)	2 (–25)	3 (–51)	1 (0)	2 (–18)	13
HB3	396 (180)	2 (–40)	2 (–25)	3 (–51)	1 (0)	2 (–18)	46
HC1	353 (137)	11 (–31)	6 (–20)	10 (–43)	1 (–1)	7 (–13)	30
HC2	330 (114)	10 (–31)	8 (–18)	13 (–40)	1 (0)	9 (–11)	13
HC3	363 (147)	10 (–31)	8 (–18)	13 (–40)	1 (0)	9 (–11)	46
Two-centre models							
C1	241 (25)	142 (100)	1 (–25)	2 (–51)	1 (–1)	1 (–19)	30
C2	237 (21)	128 (86)	2 (–25)	3 (–51)	1 (0)	2 (–18)	13
C3	256 (40)	142 (100)	2 (–25)	3 (–51)	1 (0)	2 (–18)	46
HA1	241 (25)	142 (100)	1 (–25)	2 (–51)	1 (–1)	1 (–19)	30
HA2	237 (21)	128 (86)	2 (–25)	3 (–51)	1 (0)	2 (–18)	13
HA3	256 (40)	142 (100)	2 (–25)	3 (–51)	1 (0)	2 (–18)	46
HB1	241 (25)	142 (100)	1 (–25)	2 (–51)	1 (–1)	1 (–19)	30
HB2	237 (21)	128 (86)	2 (–25)	3 (–51)	1 (0)	2 (–18)	13
HB3	256 (40)	142 (100)	2 (–25)	3 (–51)	1 (0)	2 (–18)	46
HC1	228 (12)	136 (94)	6 (–20)	10 (–43)	1 (–1)	7 (–13)	30
HC2	220 (4)	121 (79)	8 (–18)	13 (–40)	1 (0)	9 (–11)	13
HC3	238 (22)	135 (93)	8 (–18)	13 (–40)	1 (0)	9 (–11)	46

configurations of wards, particularly when there are small numbers concerned.

- Such problems are particularly pronounced in specialist areas such as an ITU where they may rely on a critical size in order to be able to manage variations in workload.
- Recipient units may not have the capacity to take increased workload without considerable step costs involved in the installation of new equipment or a new building to provide ward or theatre space.
- The effects of volume on costs may work in both directions with economies of scale in central units but inefficiencies produced in units that are to lose workload. The issue of such economies is discussed below.

Such issues would need to be considered separately in particular units. The provision of health services is in a constant state of flux and it is quite likely that many of the issues referred to above could be dealt with through a managed

TABLE 67 *Total number of outpatient visits required per year (and change from base case) for each of the options considered in the model*

	Sheffield	Doncaster	Barnsley	North Derbyshire	Worksop	Rotherham	Net
Base case	6246 (0)	2267 (0)	1240 (0)	1989 (0)	259 (0)	1549 (0)	0
Single-centre models							
D1	5672 (–574)	2423 (155)	1392 (152)	2097 (108)	259 (0)	1708 (160)	0
D2	5952 (–294)	2588 (321)	1624 (385)	2601 (612)	252 (–7)	1874 (325)	1342
D3	6075 (–171)	2590 (323)	1624 (385)	2601 (612)	252 (–7)	1874 (325)	1467
C1	10,504 (4258)	966 (–1302)	527 (–713)	764 (–1225)	250 (–9)	682 (–867)	143
C2	11,657 (5411)	963 (–1305)	541 (–699)	786 (–1203)	252 (–7)	693 (–856)	1342
C3	11,782 (5536)	963 (–1305)	541 (-699)	786 (–1203)	252 (–7)	693 (–856)	1467
HA1	4342 (–1904)	2547 (280)	1578 (339)	2476 (487)	737 (478)	2012 (463)	143
HA2	4342 (–1904)	2640 (372)	1869 (630)	3015 (1026)	852 (592)	2175 (626)	1342
HA3	4342 (–1904)	2660 (393)	1904 (665)	3051 (1062)	861 (601)	2198 (650)	1467
HB1	4342 (–1904)	2547 (280)	1578 (339)	2476 (487)	737 (478)	2012 (463)	143
HB2	4342 (–1904)	2640 (372)	1869 (630)	3015 (1026)	852 (592)	2175 (626)	1342
HB3	4342 (–1904)	2660 (393)	1904 (665)	3051 (1062)	861 (601)	2198 (650)	1467
HC1	4342 (–1904)	2547 (280)	1578 (339)	2476 (487)	737 (478)	2012 (463)	143
HC2	4342 (–1904)	2640 (372)	1869 (630)	3015 (1026)	852 (592)	2175 (626)	1342
HC3	4342 (–1904)	2660 (393)	1904 (665)	3051 (1062)	861 (601)	2198 (650)	1467
Two-centre models							
C1	7105 (859)	4364 (2097)	527 (–713)	764 (–1225)	250 (–9)	682 (–867)	143
C2	7900 (1654)	4720 (2453)	541 (–699)	786 (–1203)	252 (–7)	693 (–856)	1342
C3	7971 (1725)	4774 (2507)	541 (–699)	786 (–1203)	252 (–7)	693 (–856)	1467
HA1	4342 (–1904)	2547 (280)	1578 (339)	2476 (487)	737 (478)	2012 (463)	143
HA2	4342 (–1904)	2640 (372)	1869 (630)	3015 (1026)	852 (592)	2175 (626)	1342
HA3	4342 (–1904)	2660 (393)	1904 (665)	3051 (1062)	861 (601)	2198 (650)	1467
HB1	4342 (–1904)	2547 (280)	1578 (339)	2476 (487)	737 (478)	2012 (463)	143
HB2	4342 (–1904)	2640 (372)	1869 (630)	3015 (1026)	852 (592)	2175 (626)	1342
HB3	4342 (–1904)	2660 (393)	1904 (665)	3051 (1062)	861 (601)	2198 (650)	1467
HC1	4342 (–1904)	2547 (280)	1578 (339)	2476 (487)	737 (478)	2012 (463)	143
HC2	4342 (–1904)	2640 (372)	1869 (630)	3015 (1026)	852 (592)	2175 (626)	1342
HC3	4342 (–1904)	2660 (393)	1904 (665)	3051 (1062)	861 (601)	2198 (650)	1467

process of change. There are many other developments and changes that are taking place in healthcare, and a gradual process, which dovetails with other such developments, may be possible.

Economies of scale

The recommended approach to costing in the public sector is to estimate the long-run marginal cost consequences of the different options.[237] This is the most appropriate perspective for informing policy and is the one adopted in this project. However, there will be variations in short-run marginal costs, which local decision makers would have to bear in mind when considering whether or not to reorganise the provision of vascular services. These would include differences in capacity and availability of suitable staff and facilities in the centre, ability to re-use or transfer staff and facilities released in peripheral hospitals, and any other costs of transition.

TABLE 68 *Estimated maximum costs (£1000s) per year (and change from base case) for each of the options considered in the model*

	Sheffield	Doncaster	Barnsley	North Derbyshire	Worksop	Rotherham	Net
Base case	5544 (0)	1604 (0)	1011 (0)	1751 (0)	135 (0)	1062 (0)	0
Single-centre models							
D1	5274 (–270)	1753 (149)	1063 (52)	1727 (–24)	135 (0)	1137 (75)	–18
D2	6422 (878)	1841 (237)	967 (–44)	1612 (–139)	117 (–18)	1034 (–28)	886
D3	6563 (1019)	1843 (239)	967 (–44)	1612 (–139)	117 (–18)	1034 (–28)	1029
C1	9899 (4355)	427 (–1177)	256 (–755)	407 (–1344)	113 (–22)	326 (–737)	320
C2	10,753 (5209)	422 (–1182)	289 (–722)	460 (–1291)	117 (–18)	354 (–708)	1288
C3	10,897 (5353)	422 (–1182)	289 (–722)	460 (–1291)	117 (–18)	354 (–708)	1431
HA1	9899 (4355)	427 (–1177)	256 (–755)	407 (–1344)	113 (–22)	326 (–737)	320
HA2	10,753 (5209)	422 (–1182)	289 (–722)	460 (–1291)	117 (–18)	354 (–708)	1288
HA3	10,897 (5353)	422 (–1182)	289 (–722)	460 (–1291)	117 (–18)	354 (–708)	1431
HB1	9000 (3457)	643 (–961)	426 (–585)	666 (–1085)	115 (–20)	536 (–526)	279
HB2	9478 (3934)	719 (–885)	545 (–466)	893 (–858)	120 (–15)	590 (–473)	1238
HB3	9622 (4078)	719 (–885)	545 (–466)	893 (–858)	120 (–15)	590 (–473)	1381
HC1	7688 (2144)	988 (–616)	639 (–372)	1018 (–733)	113 (–22)	814 (–249)	153
HC2	7902 (2358)	1051 (–553)	835 (–176)	1368 (–382)	117 (–18)	931 (–132)	1097
HC3	8045 (2501)	1051 (–553)	835 (–176)	1368 (–382)	117 (–18)	931 (–132)	1240
Two-centre models							
C1	6432 (888)	3894 (2290)	256 (–755)	407 (–1344)	113 (–22)	326 (–737)	320
C2	7074 (1530)	4100 (2497)	289 (–722)	460 (–1291)	117 (–18)	354 (–708)	1288
C3	7156 (1612)	4162 (2558)	289 (–722)	460 (–1291)	117 (–18)	354 (–708)	1431
HA1	6432 (888)	3894 (2290)	256 (–755)	407 (–1344)	113 (–22)	326 (–737)	320
HA2	7074 (1530)	4100 (2497)	289 (–722)	460 (–1291)	117 (–18)	354 (–708)	1288
HA3	7156 (1612)	4162 (2558)	289 (–722)	460 (–1291)	117 (–18)	354 (–708)	1431
HB1	6024 (480)	3620 (2016)	426 (–585)	666 (–1085)	115 (–20)	536 (–526)	279
HB2	6411 (867)	3786 (2182)	545 (–466)	893 (–858)	120 (–15)	590 (–473)	1238
HB3	6493 (949)	3848 (2244)	545 (–466)	893 (–858)	120 (–15)	590 (–473)	1381
HC1	5413 (–131)	3263 (1659)	639 (–372)	1018 (–733)	113 (–22)	814 (–249)	153
HC2	5585 (41)	3367 (1764)	835 (–176)	1368 (–382)	117 (–18)	931 (–132)	1097
HC3	5667 (123)	3429 (1825)	835 (–176)	1368 (–382)	117 (–18)	931 (–132)	1240

In the long run all costs vary and, in the absence of economies of scale, long-run marginal costs are usually proxied by average costs.[238] This justifies the methods adopted in this study for estimating the likely cost consequences for intensive care, ward care and time in theatre. It is based on the assumptions that over the long run all resources can be redeployed. Therefore, the reduction in days on the ITU or general ward will release bed space, which will be occupied by other patients or result in a proportionate change in costs via reductions in staffing and accommodation.

The equivalence of marginal with average costs in long-run equilibrium is a well known result in economic theory in the context of competitive firms. For large public enterprises such as hospitals, long-run cost functions are usually assumed to be 'L' shaped. The evidence in relation to hospitals was reviewed by the York Health Economics Consortium and

TABLE 69 *Estimated minimum costs (£1000s) per year (and change from base case) for each of the options considered in the model*

	Sheffield	Doncaster	Barnsley	North Derbyshire	Worksop	Rotherham	Net
Base case	4862 (0)	1401 (0)	879 (0)	1525 (0)	114 (0)	933 (0)	0
Single-centre models							
D1	4609 (–253)	1534 (133)	930 (51)	1509 (–16)	114 (0)	1002 (69)	–16
D2	5623 (760)	1615 (214)	853 (–26)	1422 (–102)	99 (–15)	912 (–21)	809
D3	5744 (882)	1617 (216)	853 (–26)	1422 (–102)	99 (–15)	912 (–21)	933
C1	8697 (3835)	359 (–1042)	216 (–663)	344 (–1180)	95 (–19)	275 (–658)	272
C2	9481 (4618)	354 (–1047)	244 (–635)	391 (–1133)	99 (–15)	299 (–633)	1155
C3	9605 (4743)	354 (–1047)	244 (–635)	391 (–1133)	99 (–15)	299 (–633)	1279
HA1	8697 (3835)	359 (–1042)	216 (–663)	344 (–1180)	95 (–19)	275 (–658)	272
HA2	9481 (4618)	354 (–1047)	244 (–635)	391 (–1133)	99 (–15)	299 (–633)	1155
HA3	9605 (4743)	354 (–1047)	244 (–635)	391 (–1133)	99 (–15)	299 (–633)	1279
HB1	7858 (2996)	561 (–840)	376 (–503)	585 (–939)	97 (–17)	473 (–459)	236
HB2	8293 (3430)	633 (–768)	484 (–395)	794 (–731)	101 (–13)	521 (–411)	1111
HB3	8417 (3554)	633 (–768)	484 (–395)	794 (–731)	101 (–13)	521 (–411)	1235
HC1	6693 (1830)	867 (–533)	565 (–314)	898 (–626)	95 (–19)	720 (–213)	124
HC2	6893 (2030)	927 (–474)	741 (–138)	1216 (–309)	99 (–15)	824 (–108)	986
HC3	7017 (2155)	927 (–474)	741 (–138)	1216 (–309)	99 (–15)	824 (–108)	1110
Two-centre models							
C1	5644 (781)	3412 (2011)	216 (–663)	344 (–1180)	95 (–19)	275 (–658)	272
C2	6227 (1365)	3608 (2207)	244 (–635)	391 (–1133)	99 (–15)	299 (–633)	1155
C3	6298 (1436)	3661 (2260)	244 (–635)	391 (–1133)	99 (–15)	299 (–633)	1279
HA1	5644 (781)	3412 (2011)	216 (–663)	344 (–1180)	95 (–19)	275 (–658)	272
HA2	6227 (1365)	3608 (2207)	244 (–635)	391 (–1133)	99 (–15)	299 (–633)	1155
HA3	6298 (1436)	3661 (2260)	244 (–635)	391 (–1133)	99 (–15)	299 (–633)	1279
HB1	5262 (400)	3157 (1756)	376 (–503)	585 (–939)	97 (–17)	473 (–459)	236
HB2	5609 (747)	3316 (1916)	484 (–395)	794 (–731)	101 (–13)	521 (–411)	1111
HB3	5680 (817)	3370 (1969)	484 (–395)	794 (–731)	101 (–13)	521 (–411)	1235
HC1	4720 (–142)	2840 (1439)	565 (–314)	898 (–626)	95 (–19)	720 (–213)	124
HC2	4875 (13)	2945 (1544)	741 (–138)	1216 (–309)	99 (–15)	824 (–108)	986
HC3	4946 (84)	2998 (1597)	741 (–138)	1216 (–309)	99 (–15)	824 (–108)	1110

published in *Effective Health Care Bulletin*, which concludes: "There is no evidence that cost savings can be secured merely by increasing scale in acute hospitals beyond 200 beds".[239] We have therefore assumed that for general resources such as ward beds, ITU beds and theatre time a flat cost function and hence long-run marginal costs equals average costs. Any deviation would be a local phenomenon and hence not relevant to the NHS as a whole.

Nonetheless there could be economies of scale in the long run arising from a more efficient use of specialist equipment and staff, where there are indivisibilities in key resources, such as items of equipment or trained personnel, which can only be used to undertake specialist vascular activities. Under the devolved option, therefore, the peripheral hospitals with their lower volumes would find these resources are underused. Under the centralised option it might be possible to achieve the same level of workload with fewer specialised staff and less specialist equipment.

However, this does not seem to be the case for vascular services. In the case of staff, specialist vascular surgeons and radiologists in peripheral hospitals make up their time by undertaking more routine work, usually in relation to general surgery or other interventional radiology. The effect of this is that there are unlikely to be economies of scale through centralisation of services, though as seen in chapter 4 (*The relationship between volume and outcome*) there may be improvements in outcome where clinicians and units carry out a greater volume of specialist work.

In terms of specialist equipment a similar situation pertains in that many smaller districts may compromise in the purchase of equipment to obtain less specialist devices that are suitable for multiple purposes. The largest single item of capital equipment that is specific to vascular services is the digital radiological imaging suite used for angiography and interventional radiology. Such equipment costs in the region of £750,000 and on average can be used for three to four cases of interventional and/or diagnostic radiology per session. Based upon the figures presented in *Table 64* it is to be expected that the required number of procedures is approximately 150 per 100,000 of population. Thus, a single interventional radiology suite should be capable of dealing with the needs of a population of about 1 million or more if extended working hours were available. A full radiology suite under the devolved arrangements would be considerably under-utilised. However, most DGHs will require digital imaging equipment for other purposes that could be used for vascular imaging. Such equipment is not ideal and is likely to limit distal imaging, necessary for femoro-distal bypasses, and the capability for more complex endovascular treatment. This may be one of the reasons that such procedures seem to be considerably less frequent in certain districts (see chapter 3, *Workload analysis*). There may also be potential risks in carrying out potentially infected bowel investigations in the same area as vascular procedures.

The implication of this is that centralisation of services is unlikely to produce significant economies of scale with respect to either staff or equipment. However, centralisation may result in a higher quality of service at an equivalent cost, due to the ability to procure more specialised equipment at an equivalent cost-per-case in a unit with high through-put and the greater sub-specialisation of staff in all disciplines

For these reasons it seems that there is little scope for achieving economies of scale in the long run from centralising vascular services.

Cost-effectiveness of specific changes

The specific issues that were raised above have been considered individually. Clearly, any reconfiguration of services needs to be considered in its entirety but separate consideration of particular issues makes it possible to identify the components of the reconfiguration of services that have the greatest potential for improvements in cost-effectiveness. By running the model and considering only changes to the rate or transfer for specific procedures, it is possible to estimate the outcome and resource implications of that specific change.

In the case of aortic aneurysms there is currently little variation in emergency admission rates and elective operation rates between centres. The issue in respect of these is related to the proportion of emergency cases undergoing surgery and the outcome of surgery for all cases. In all centralised and hub and spoke models it is assumed that aortic surgery would be carried out in the central unit. The model suggests that this would result in the centralisation of 58 emergency and 59 elective aneurysm repairs across the whole of North Trent. This would have an estimated additional cost, which is largely due to the additional emergency cases undergoing surgery, and thus having extended stay and ITU requirements. Based upon the differences in mortality given in *Table 19* this may be expected to save just over 20 lives at an estimated cost of between £4371 and £5396 per life saved.

For PVD the effects of changes in practice to match those in the central hospital show that there would be expected to be a reduction in the number of major amputations of approximately 65 with an increased proportion being at the below-knee level. There would be an increase in the total number of vascular reconstructions but a reduction in those using prosthetic grafts and a 12.5% increase in the number of angioplasties. It is difficult to put figures on the likely benefit of these changes, but some attempt to do so can be made, based upon the decision modelling reported in chapter 5 (*Decision analysis*). Considering only the case of amputation the expected improvement of quality-adjusted life expectancy by avoiding the need for amputation is approximately 2.0 QALYs. In the case of angioplasty the gain from using it as an alternative to surgery for critical ischaemia was estimated at approximately 0.44 QALY and for short-distance claudication at 0.1 QALY. These give estimates of £6601 to £8970 per QALY gained, depending upon the estimates of cost and the situation under consideration. There are possible additional benefits connected with the change in level of amputation, the graft material and extra procedures for ischaemic symptoms, which have not been quantified.

In the case of carotid surgery the results suggest that an additional 42 carotid operations would be carried out, which, on the basis of the published studies described in chapter 4 (*Carotid endarterectomy*), would save approximately seven strokes at a cost of £17,700 to £20,500 per stoke avoided.

It is essential to note that these calculations are purely from the perspective of the reorganised vascular service. From an overall health service or societal perspective a reduction of amputation or stroke rates is likely to be very cost-effective due to the high cost of subsequent treatment and care. However, as with many other situations, the practicalities of the situation make it unlikely that costs saved in other areas could be identified and used to fund the reconfiguration of vascular services.

Chapter 8

Discussion and conclusions

There are a number of other issues that may need to be taken into account when considering the reconfiguration of services.

Linkages

In any possible reconfiguration of service provision there are a number of issues to consider regarding the linkages of different medical services. In the case of vascular services there are numerous other specialities with which there are potential linkages, though many of these are of relatively small volume. Linkages may occur in both directions in that there are many specialities that may require the support of vascular surgeons or radiologists and there are other specialities that may be required to support vascular surgery. The following is a description of some of these linkages.

- Vascular surgery needs close links with vascular radiology with access to angiography and angioplasty.
- Other vascular investigations are required, which include duplex vascular assessment, abdominal ultrasound, cardiac assessments and imaging such as magnetic resonance imaging and spiral computed tomography.
- Major vascular surgery requires adequate ITU and preferably HDU support.
- Renal services may be required by vascular patients, particularly those undergoing emergency aortic surgery. Renal services also frequently require the support of vascular services for patients with co-existing vascular disease, radiological support for vascular access, and in some places vascular surgeons are responsible for maintaining a vascular access service.
- Vascular services need the support of physicians for many of their patients and there are particularly close links in respect to diabetic services. Ideally there may be joint clinics for the management of patients with diabetic foot problems.
- Patients with leg ulceration may be jointly dealt with by dermatologists and vascular surgeons.
- Amputees and elderly patients with vascular reconstruction need rehabilitation services.
- Surgeons and radiologists need to work closely with neurologists in the management of patients with carotid disease
- There are many other services that occasionally require urgent vascular surgical assistance including trauma and orthopaedics, cardiac surgery and other general and gynaecological surgeons

Training

Over the past few years there have been substantial changes in surgical training. One of the main implications of this is that the training has become shorter and more concentrated.

Historically, general surgical trainees had training in all the sub-specialist areas of general surgery. New training arrangements mean that they are more likely to be trained in a sub-specialist area and have little experience of other sub-specialities.[240] The appropriate training for a vascular specialist has been discussed by the Vascular Surgical Society and has now been formulated in some detail.[241] This relies on specialist training centres with a full range of resources. The implication of these changes is that there is no longer a supply of trainees with general surgical experience who are suitable for mixed posts with a small component of vascular surgery.[242] It is also likely that surgeons trained in other sub-specialities such as breast and colorectal surgery will have received little or no training in vascular techniques and could not be expected to deal with vascular emergencies as part of a general surgical on-call rotation.

Very similar issues arise for vascular radiologists in that there is an increasing demand for specialist vascular investigation and treatment, often as an emergency and general radiologists may not have been adequately trained in these specialist areas.

Such problems are not confined to the UK but have raised issues about organisation,[243–245] demarcation of responsibilities[246,247] and the organisation of training in other countries.[245,248]

Research and development

In the past there have been problems within surgery as a result of the introduction of new technology in a haphazard way. There is now somewhat clearer regulation of the introduction of new technology through the Safety and Efficacy Register of New Interventional Procedures,[249] and with this and the introduction of the National Institute for Clinical Excellence[250] it is possible that new developments will be introduced in a more coordinated way with appropriate training and pilot studies. As seen from the analysis of workload above, the current arrangement means that several centres have quite limited experience of certain areas of vascular surgery, which may make it difficult to carry out adequate training or research and development in these centres.

In vascular surgery and radiology there has been a very rapid development in new technology over the past few years and there are some very major changes in management likely with the introduction of endovascular techniques for the management of both aneurysmal and occlusive disease.

Summary of options

The aim in this paper is to consider the effects of the organisation of vascular services on cost and outcomes. Three main options have been identified and each of these will be discuss below as regards their main advantages and disadvantages.

Devolved service

The devolved service, which reflects the current situation in most places, is already undergoing a number of changes. For the reasons described above, particularly the issues regarding training and expertise, a fully devolved service has proved impossible to maintain. The main problems with such a service include the following.

- The high volume of emergency and urgent work makes it difficult to support a service without a critical mass of specialist surgeons and radiologists to provide on-call arrangements.
- The changes in the training system make it unlikely that newly appointed surgeons and radiologists without specialist training will be in a position to continue to support the service.
- The development of new technologies, which require experience, training and/or specialist equipment with high capital costs, will make it difficult for a full service to be offered in all small centres.
- The need to have adequately documented workload and outcomes in order to demonstrate the quality of the service for the purposes of clinical governance and performance review, make it unlikely that specialists carrying out very low volumes will be able to continue to practice in this way.
- The evidence suggests that a devolved service gives rise to considerable variability in access to particular procedures.

For these reasons there is already a move away from a fully devolved service within North Trent. The NGH already has a hub and spoke arrangement for providing services to Worksop and an arrangement with Rotherham for the support of vascular emergency services.

The modelling of the formalisation of the devolved service (D1) suggests that the current flows out of the smaller districts are not sufficient to justify significant additional staff at these centres that would make the provision of a full emergency service a realistic possibility. The models, which assume an increase in activity to match the central rates (D2 and D3), demonstrate that, even if it were possible to achieve these rates, the overall activity would be insufficient to justify the additional staff necessary to provide full emergency cover. Activity in key areas would also remain below that necessary to maintain the necessary skills to offer a full range of services. It seems likely that increasing scrutiny of clinical results will make it difficult for major vascular surgery to be carried out in centres with sub-optimal levels of experience and a lack of specialist out-of-hours cover.

The main advantage of a devolved service is that it goes some way to meet the strong preference that has been found for the provision of local services. However, the evidence suggests that in several respects the devolved service offers a limited range of local service with reduced access to those services that are not provided locally.

Centralised service

The model for a fully centralised service is similar to that seen for cardiac services in many places, with regional or sub-regional centres offering a full range of services. Based on the review of the evidence, such a service should provide the highest possible quality in terms of outcome with large volumes going through a specialist centre. Such a model also gives an arrangement whereby a high-quality specialist training can be provided and the workload is concentrated in one area, which has advantages for research and development.

There are a number of potential disadvantages with the centralised arrangement.

- It is clear from the conjoint analysis that patients put a high value of the provision of local services and under this arrangement there is the maximum travelling by patients.
- It seems likely that the full centralisation of a service will, if anything, exacerbate the existing variability in access to services. This has been demonstrated for cardiac services in the past[18] and the evidence from the present study is that areas that do not have particular services offered locally provide reduced access to such services.
- The arrangement may provide poor vascular support to other services that have not been centralised.
- It is possible that delays in transfer of emergency cases to a centralised unit will result in poorer outcomes. However the data from this current study and from published reports do not support this.[42,67,251] The generally held view is that travelling times of up to 1 hour make very little difference to the outcome in even the most urgent cases.[29]

Hub and spoke arrangement

The hub and spoke arrangement provides a central unit with a number of services being provided locally. Because of the centralisation of the highly specialist and complex cases it is to be expected that the outcomes in this respect would be similar to the centralised service.

In terms of the problems described for a centralised service the hub and spoke arrangement would be expected to have certain advantages.

- Although patients would still need to travel to the centre for major procedures, the outpatient services and some diagnostic and minor procedures would be provided locally, which would considerably reduce the travelling required.
- This arrangement would be expected to give the best possible access to services, particularly if provided by an in-reach or out-reach facility. The presence of specialists working at both the hub and the spoke hospital would be likely to produce working practices that were consistent between the two. The links between the hub and spoke would also provide a useful education role in giving feedback to medical, nursing and other staff within the spoke hospital and contact with local general practitioners.
- The presence of the specialist at the spoke hospital would also give access to other specialities for urgent referrals for ward patients for joint clinics where these were felt to be appropriate.
- From the data that have been analysed it is estimated that the workload of a district servicing a population of 200,000–300,000 would generate a vascular outpatient workload of approximately two vascular outpatient clinics per week. If the vascular surgeon was also responsible for a proportion of the varicose vein service and carried out day-case procedures at the spoke hospital this would provide an arrangement whereby there was a specialist surgeon on site at the spoke hospital for 2–3 days per week. This is sufficient to provide an urgent service for most ward referrals and would provide cover for emergencies arising from radiological procedures carried out on the site.

Three sub-options were considered for hub and spoke arrangements, depending upon the range of procedures that are available in the spoke hospital. The modelling shows relatively small cost differences between these options, the main differences being in terms of the shift of activity and corresponding resources from the spoke to the hub hospital. The estimates for resource use and cost are based upon the working practices and resource use in the hospital to which the work is transferred. Thus, the differences between these sub-options reflect the different resource use at the specific hospitals. As discussed in chapter 7 (*Resource use*), some of the differences in resource use may reflect a current selective referral practice resulting in casemix differences. If this is the case then the effect would be to narrow the already small gap between the resource implications of these options.

If the hub and spoke arrangement were to be implemented then the choice between these sub-options will depend largely upon local circumstances and availability of suitable facilities. For example, within North Trent, Worksop has no facilities for angiography and would be unlikely to have the volume of work or expertise to justify such a development, thus making option HA the only viable arrangement. In Barnsley the second arrangement (HB) may be suitable, there being existing equipment and expertise suitable for angiography. In Rotherham there could be an argument for maintaining some elective vascular surgery (HC), with some vascular surgical expertise 'on-site' and a short distance to the central unit if urgent transfer were necessary. These options are not, therefore, mutually exclusive but may co-exist within the same organisational framework.

Single and two-centre arrangements

All the centralised and hub and spoke arrangements were considered as both single-centre and two-centre alternatives, as discussed in chapter 7 (*Scenarios for care*). The models assume that, were there to be a second specialist vascular centre, the costs, working practices and outcomes of both would be similar. In practice the number of specialist centres that can be supported will depend upon local circumstances, geography and population distribution. No evidence has been found in the literature to support or refute the contention that there is any beneficial or detrimental effect on cost or outcome for centres that exceed the size required to maintain a full emergency surgical and radiological service. Thus, it would seem logical to organise centres in such a way as to maximise the availability of local services.

There are, however, some concerns about the practicalities of developing services based upon multiple specialist centres. One major concern is that the current arrangements may make it difficult for referral practices to be forced to support the desired patterns of work. For example, the proposed two-centre option in North Trent would rely upon the referral of patients from Worksop and Rotherham to maintain the viability of the second central unit at Doncaster. It is questionable whether this arrangement would be acceptable to the referring practitioners and patients of these centres, as there has been a history of referral to the established vascular unit in Sheffield, which is closer and has easier transport links for most inhabitants of these districts.

Other concerns regarding the ability to deliver such arrangements relate to the increasing subspecialisation within vascular services, the linkages to other specialist services and training and recruitment issues. Clearly, such planning needs to be coordinated with the configuration of other services and would require a considerable degree of central control.

Managing service reconfiguration

All health services are in a constant state of change due to the rate of technical development, the emergence of new research findings and alterations in policy, priority or the philosophy underpinning the provision of services. However, in many aspects of the service change is slow due to delays in the implementation of research findings, conflicting pressures and priorities, limitations in resources and the long time periods required for staffing changes that may depend upon retirements or retraining. Thus, when considering the reconfiguration of vascular services, it is important to consider the practicalities and time scale of developing each of the possible options.

Although the devolved service is the closest to the current arrangements in most places, as discussed above in *Devolved services*, there are a number of pressures that will make it difficult to maintain such services. The greatest difficulty is likely to be in providing an adequate supply of suitably trained staff with the necessary skills to provide such services. A number of centres have already found difficulty in filling posts and a review of current surgical trainees' expectations has shown a strong preference for posts that are largely or entirely devoted to vascular surgery and are in larger centres.[242]

Full centralisation of services is likely to be difficult to achieve in the short term. In most situations, the reconfiguration of services in this way would require the transfer of considerable resources and the movement or redundancy of staff. Such arrangements are also likely to have considerable cost implications in terms of step costs for the centralised unit and the costs of redundancies or redeployment of staff at the smaller centre. Large-scale transfer of services would also be likely to result in local opposition, and experience has shown that it is difficult to make such changes without considerable delays. It is also difficult to envisage a staged process, for example partial centralisation when a new consultant appointment is made, as the problems for the residual, devolved, part of the service would be exacerbated.

In many ways hub and spoke arrangements provide the easiest route to reconfiguration. There are, as described in chapter 7 (*Scenarios for care*), a variety of ways in which such arrangements can be provided, and this allows a more flexible and acceptable approach to reconfiguration of services. Although it may be possible and appropriate to fully reconfigure services at one time, there are a number of stages that could allow a gradual process to take place where this is more appropriate to local needs. These stages include:

- development of shared arrangements to deal with emergency vascular admissions
- development of out-reach services for outpatient clinics, day-case operating lists, diagnostic radiological services and local consultation for other specialities
- provision of in-reach services with theatre time and support provided for staff from the spoke hospital to carry out major procedures at the hub
- joint appointments to new or replacement posts, with sessions in both hub and spoke hospitals
- formal arrangements for the tertiary referral of particular diagnostic groups or procedures
- arrangements for the transfer of convalescent patients to a local spoke hospital.

Such changes could be carried out in a gradual and piecemeal fashion. There may, however, be areas in which suitable reciprocal arrangements could offset the need for shifting resources. For example, the provision of out-reach day-case operating lists and diagnostic radiological services may be tied to the provision of in-reach services for major vascular surgery or complex radiology at the hub hospital. Similarly, where there is currently an existing element of centralised activity, the resource implications of acute or major cases that are transferred to the centre may be partially offset by reciprocal arrangements that enable rehabilitation and convalescence to be carried out locally.

Conclusions

This study has considered many aspects of the organisation of vascular services both from a local perspective and from a review of published evidence. A number of issues have been identified that are likely to be relevant to reconfiguration of such services.

- The consultant questionnaire identified differences in the availability of particular services and in local working practices.
- The analysis of workload gave a detailed analysis of current rates of particular procedures for use in the modelling exercise. It also demonstrated and quantified differences in availability of particular procedures and in local working practices.
- An analysis of outcomes showed considerable variation in a number of indicators of outcome, such as mortality following aortic surgery and amputation rates. Literature reviews suggested that these were more than a local phenomenon but are in fact a reflection of systematic differences in outcome that may be related to the configuration of services.
- Utility analysis and the use of decision analysis allowed the outcome of different treatments to be compared. Conjoint analysis demonstrated a strong preference among patients with moderate or mild PVD for the local availability of treatment, and showed that patients would appear to be prepared to trade-off significant reductions in the expected outcome for the local availability of services. However, the magnitude of some of the differences in outcome described above was greater that the acceptable trade-off found in this exercise.
- Modelling of possible options for the reconfiguration of services allowed the quantification of the resource requirements and possible benefits of specific changes in configuration. This modelling exercise suggested that the benefits that were likely to accrue from centralisation of services or hub and spoke arrangements were well within the bounds of other interventions that have previously been considered to be cost-effective.
- The modelling suggested that a fully centralised service would appear to have little in the way of cost or outcome advantages over a hub and spoke arrangement and would have considerable disadvantages in terms of the clear preferences that patients expressed for the provision of local services. Most of the cost and resource requirements, associated with the different models, relate to increased use of particular procedures and greater access to services. Thus, any local initiatives that may improve services in a similar way but within the current devolved structure would be likely to be associated with similar costs.
- A centralised or hub and spoke arrangement would appear to have advantages from the point of view of training, research and development.
- A hub and spoke arrangement could be developed in a number of steps without the need for a sudden large movement of resources.

It seems that the present situation will be untenable in the long term due to current changes in training and the requirements of clinical governance. These are largely outside the control of those planning the service in that they relate to national or international policies regarding medical training, working hours and performance review. There is a need for a structured move towards a formalised system that allows adequate access to specialist emergency services, that ensures equality of access to treatments that are proven to be effective and that will help to facilitate the introduction of new clinical developments.

There is likely to be a trade-off in this process between the desire to provide such services locally in order to comply with patients' wishes and the need for some degree of sub-specialisation in order to produce the optimum clinical outcomes.

The hub and spoke arrangement would appear to be the most likely compromise solution, with the range of services available at the spoke hospital being adjusted to meet local circumstances and facilities. For example, in a district with a population of 200,000–300,000 it may be feasible to provide local facilities for diagnostic angiography, day-case varicose veins and minor amputations. The estimated workload would allow there to be a vascular specialist present on site for 2–3 days per week in order to cover the radiological service, provide access to linked services on the wards and to carry out the outpatient clinics and day-case operating lists. For smaller districts it may be that suitable radiological facilities would not be available but that some outpatients and day-case operating would still be appropriate. Larger units may have sufficient workload to justify a greater range of inpatient vascular services but with tertiary referral for more complex cases.

Vascular services need to be developed in a planned and coordinated fashion, taking account of a large number of different frequently conflicting pressures. In planning such a service there are a large number of considerations and **appendix 6 provides some evidence-based guidance** that may be used as a check-list when considering reconfiguration of services and possible local arrangements. This takes into account a large number of issues examined in this project and other relevant points from the published evidence.

The study has demonstrated a number of problems stemming from the current configuration of vascular services, which are leading to excess mortality and morbidity, including limb loss and stroke. With the development of clinical governance there is an onus on all purchasers and providers of vascular services to ensure that there are robust arrangements in place to ensure the provision of vascular services. This should include a full range of emergency and elective surgical and radiological procedures provided by personnel with the necessary training, expertise and support.

Although the study was based on a specific model for the hospital districts in North Trent, many of the considerations are widely applicable to areas in the UK and elsewhere. The overall message is that the development of a rational, centrally planned specialist vascular service could provide considerable improvement in patient outcomes with acceptable cost-effectiveness.

Recommendations for research

This project has identified a number of areas in which further research and development work would be beneficial.

Coding systems

The current coding systems were found to have a number of inadequacies in describing casemix in vascular surgery. These difficulties largely stem from the fact that the systems were not designed primarily for use in developing performance indicators and do not therefore take account of important issues of casemix. There is need for further research to look at methods for correcting for casemix, modification of the routinely collected data set and to look at new coding systems, such as Read coding[23] and POSSUM scoring[24] in terms of its possible application in this respect.

Data quality has been a major cause for concern in this study and further work should be undertaken to assess the accuracy of routinely collected data and methods for monitoring and improving on future data collection.

There is a need to develop rapid systems to identify and monitor the introduction of new technologies. The project has identified several new developments within vascular surgery, such as carotid artery stenting, endovascular aneurysm repair and intra-arterial thrombolysis, which are not easily identified using existing coding systems.

Limb salvage

This and other studies have shown considerable difference in the rate of limb salvage. However, the deficiencies in the data limit the applicability of these findings. There is a need for a systematic review of the existing literature on the subject and a prospective study of patients with critical ischaemia to evaluate the cost-effectiveness of various interventions including femoro-distal bypass. The nature of this problem makes it unlikely that an RCT would be appropriate due to the ethical and practical difficulties in randomising patients to primary amputation and a prospective data collection and decision modelling approach may be more applicable.

The treatment of intermittent claudication

The study has shown considerable differences in the management of intermittent claudication in terms of the use of surgical and radiological techniques. There is a clear need for a full assessment through RCTs and economic analysis to assess the cost-effectiveness of the various available treatments for the management of intermittent claudication.

Access to services

The project demonstrates the differences in access to services between different districts. There is a need for a systematic review to identify existing evidence regarding the factors that influence access to services (e.g. for CE) and possible measures that may influence this. This may be an area where initial qualitative research would be appropriate if the systematic review were inconclusive.

Patient preferences

This study has suggested that patients have strong preferences for aspects of the service other than those generally considered in carrying out cost-effectiveness analysis. There are a number of issues in this respect that would benefit from further investigation, including:

- the nature and determinants of patient preferences, including patient demographic factors, age and co-existing illness
- patient comprehension of presented scenarios, for example the systematic differences between different formats or media for presentation such as health state descriptions, written scenarios and video interviews
- patient comprehension and attitudes regarding risk, and probabilities
- the methodological issues surrounding the elicitation of patient preferences and ways of incorporating such preferences into cost-effectiveness analysis, including comparisons between preferences based upon conjoint analysis, accepted methods of deriving QALYs, willingness to pay and Healthy Year Equivalents approaches.

Other services

There are many other small specialities that may face similar issues in regard to sub-specialisation. Systematic literature reviews may help to clarify the issues that are common to all areas in this respect and to identify evidence regarding the relationship between volume and outcome in other disciplines. The methodology developed for the review in chapter 4 (*The relationship between volume and outcomes*) could be applied elsewhere in this respect.

Costs and cost-effectiveness

We have commented on the poor quality of the published cost studies and therefore recommend that vascular journals incorporate guidelines similar to those developed by the BMJ Economic Evaluation Working Party.

Regarding the routine costing data on vascular services as a whole we recommend need for an improved classification of workload for linking to the use of key resources.

There is a need for more work to identify the cost-effectiveness of particular aspects and potential developments in vascular services. Particular examples are the treatment of critical ischaemia and the introduction of endovascular techniques.

Future developments

The study has highlighted the problems in adapting services to deal with technological and working practice developments, particular in respect of workforce planning and organisation changes, which both have long lead times. For example, if shown to be effective, new techniques such as intra-arterial thrombolysis and endovascular aortic aneurysm repair may have a major impact on the needs for the configuration of vascular services.

This requires that there is a continuing programme of horizon scanning to look at the potential impact of such treatments, a system for identifying and monitoring the use of new and novel techniques along with operational and/or cost-effectiveness modelling to predict the future impact of such developments.

Acknowledgements

This research was commissioned by the NHS R&D HTA programme. We are grateful for the comments received from the HTA referees. The authors also wish to acknowledge the support of all the surgeons, radiologists and managers in North Trent who have provided help and information for this project. Also Chris Knight at the School of Health and Related Research for his help in the operational modelling and Julie Patchett and Andrea Watson at the NGH for help with the financial data.

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Appendix 1

Casemix definitions

The final casemix definitions are based upon the OPCS procedural codes, ICD10 codes, speciality and method of admission. The table gives a list of the casemix groups corresponding to individual codes with an indication of the frequency with which individual OPCS codes occur as the primary procedure in the entire dataset, representing all episodes in Trent over the 2-year period 1995–97.

The following are the additional considerations used in defining the casemix groups.

- **Supra-renal aortic surgery and surgery to the visceral vessels (Supra-renal, etc.)** Those cases with the relevant OPCS codes in any position were identified. Both emergency and elective cases were combined due to the small number of cases and all specialities were included as review of individual cases showed that thoraco-abdominal aneurysm repairs were sometimes carried out as joint procedures with cardiothoracic surgeons and appeared under speciality code 170.
- **Intra-abdominal vascular surgery/emergency admissions (Aortic)** All episodes that had the relevant OPCS codes or a primary diagnosis of I713 or I714 were included if the mode of admission was emergency or transfer from another provider.
- **Intra-abdominal vascular surgery/elective admissions (Aortic)** All episodes that had the relevant OPCS codes or a primary diagnosis of I713 or I714 were included if the mode of admission was elective.
- **Carotid surgery (Carotid)** All episodes that had the relevant OPCS codes were included. This includes carotid angioplasty for the reasons discussed in the text.
- **Upper limb surgery (Upper limb)** All episodes that had the relevant OPCS codes or a primary diagnosis of I713 or I714 were included if the mode of admission was elective.
- **Varicose veins (VVs)** All episodes that had the relevant OPCS codes were included. Sclerotherapy was not included, as there were very few episodes and most centres carry this out as an outpatient procedure.
- **Major amputation (Major amp)** All episodes that had the relevant OPCS codes were included and spilt into two groups depending upon whether the mode of admission was elective or emergency/transfer. Amputations where the treatment speciality was plastic surgery (160) or orthopaedic surgery (110) were excluded.
- **Femoro-distal reconstruction (Femoro-distal)** All episodes that had the relevant OPCS codes were included and spilt into two groups depending upon whether the mode of admission was elective or emergency/transfer.
- **Other vascular reconstruction (Reconstruction)** All episodes that had the relevant OPCS codes were included and spilt into two groups depending upon whether the mode of admission was elective or emergency/transfer.
- **Minor amputation (Minor amp)** All episodes that had the relevant OPCS codes were included and spilt into two groups depending upon whether the mode of admission was elective or emergency/transfer. Amputations where the treatment speciality was plastic surgery (160) or orthopaedic surgery (110) were excluded.
- **Angioplasty/endovascular (Angioplasty)** All episodes that had the relevant OPCS codes were included and spilt into two groups depending upon whether the mode of admission was elective or emergency/transfer.
- **Angiography** All episodes that had the relevant OPCS codes were included and spilt into two groups depending upon whether the mode of admission was elective or emergency/transfer. Episodes were restricted to those where the speciality code was not cardiology (320) or cardiothoracic surgery (170) and episodes where there was a cardiothoracic procedure in another procedural field (K...) or a cardiac primary diagnosis (.....) were also excluded.

In order to assign episodes to the appropriate casemix group the definitions used below were applied. Classification was based upon the most severe casemix category as identified by a relevant procedure in any of the procedural code fields of the dataset. The hierarchy used, in descending order of priority, was as follows.

- Supra-renal, etc.
- Aortic
- Major amp
- Femoro-distal
- Reconstruction
- Carotid
- Upper limb
- Minor amp
- Angioplasty
- Angiography
- VVs

TABLE 70

OPCS	Text	Casemix group	Elective	Emergency	Total
L161	EMERG.BYPASS/AORTA BY ANASTOMOSIS/AXILLARY ART.FEMORAL ART	Reconstruction	2	7	9
L162	BYPASS/AORTA BY ANASTOMOSIS/AXILLARY ART.FEMORAL ART.NEC	Reconstruction	20	25	45
L168	OTHER SPECIFIED EXTRAANATOMIC BYPASS OF AORTA	Reconstruction	2	0	2
L169	UNSPECIFIED EXTRAANATOMIC BYPASS OF AORTA	Reconstruction	1	0	1
L181	EMERG.REPLACEMENT/ANEURYSMAL SEG/ASCEND.AORTA BY ANAST/AORTA		4	7	11
L182	EMERG.REPLACE/ANEURYSMAL SEG/THORACIC AORTA.ANAST/AORTA NEC	Supra-renal etc.	0	0	0
L183	EMERG.REPLACE/ANEURYSMAL SEG/SUPRARENAL ABDOMIN.AORTA.ANAST.	Supra-renal etc.	1	7	8
L184	EMERG.REPLACE/ANEURYSMAL SEG/INFRARENAL ABDOMIN.AORTA.ANAST.	Aortic	2	92	94
L185	EMERG.REPLACE/ANEURYSMAL SEG/ABDOMINAL AORTA ANAST/AORTA NEC	Aortic	4	105	109
L186	EMERG.REPLACE/ANEURYSMAL BIFURCATION/AORTA ANAST/AORT.IL.ART	Aortic	1	47	48
L188	OTHER SPECIFIED EMERG.REPLACE/ANEURYSMAL SEGMENT/AORTA	Aortic	4	15	19
L189	UNSPECIFIED EMERG.REPLACE/ANEUTYSMAL SEGMENT/AORTA	Aortic	2	46	48
L191	REPLACE/ANEURYSMAL SEG/ASCEND.AORTA ANAST/AORTA.AORTA NEC		13	8	21
L192	REPLACE/ANEURYSMAL SEG/THORACIC AORTA.ANAST/AORTA.AORTA NEC	Supra-renal etc.	4	4	8
L193	REPLACE.ENT OF ANEURYSMAL SEGMENT OF SUPRARENAL ABDOMINAL AO	Supra-renal etc.	1	3	4
L194	REPLACEMENT OF ANEURYSMAL SEGMENT OF INFRARENAL ABDOMINAL AO	Aortic	112	24	136
L195	REPLACEMENT OF ANEURYSMAL SEGMENT OF ABDOMINAL AORTA BY ANAS	Aortic	136	35	171
L196	REPLACEMENT OF ANEURYSMAL BIFURCATION/AORTA BY ANAST/AORTA	Aortic	127	25	152
L198	OTHER SPECIFIED REPLACEMENT OF ANEURYSMAL SEGMENT OF AORTA	Aortic	24	6	30
L199	UNSPECIFIED REPLACEMENT OF ANEURYSMAL SEGMENT OF AORTA	Aortic	47	12	59
L201	EMERG.BYPASS/SEG/ASCENDING AORTA-ANAST/AORTA-AORTA NEC		0	4	4
L202	EMERG.BYPASS/SEG/THORACIC AORTA ANAST/AORTA.AORTA NEC	Supra-renal etc.	0	0	0
L203	EMERG.BYPASS/SEG/SUPRARENAL ABDOMIN.AORT.ANAST/AORT.AORT NEC	Supra-renal etc.	0	1	1
L204	EMERG.BYPASS/SEG/INFRAREN.ABDOM.AORTA.ANAST/AORTA.AORTA NEC	Aortic	1	1	2
L205	EMERG.BYPASS/SEG/ABDOM.AORTA.ANAST/AORTA.AORTA NEC	Aortic	0	1	1
L206	EMERG.BYPASS/BIFURCATION/AORTA.ANAST./AORTA.ILIAC ART NEC	Aortic	0	2	2
L208	OTHER SPECIFIED EMERG.BYPASS OF SEG.OF AORTA	Aortic	0	0	0
L209	UNSPECIFIED EMERG.BYPASS OF SEGMENT OF AORTA	Aortic	0	1	1
L211	BYPASS/SEG/ASCENDING AORTA BY ANAST/AORTA TO AORTA NEC		1	0	1
L212	BYPASS/SEG/THORACIC AORTA BY ANAST/AORTA TO AORTA NEC	Supra-renal etc.	0	0	0
L213	BYPASS/SEG/SUPRARENAL ABDOMIN.AORTA ANAST.AORTA TO AORTA NEC	Supra-renal etc.	0	1	1
L214	BYPASS/SEG/INFRARENAL ABDOMIN.AORTA ANAST.AORTA.AORTA NEC	Aortic	3	1	4
L215	BYPASS/SEG/ABDOMINAL AORTA ANAST. OF AORTA.AORTA NEC	Aortic	1	0	1
L216	BYPASS/BIFURCATION/AORTA BY ANAST/AORTA TO ILIAC ARTERY NEC	Aortic	23	3	26
L218	OTHER SPECIFIED BYPASS OF SEGMENT OF AORTA	Aortic	7	1	8

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
L219	UNSPECIFIED OTHER BYPASS OF SEGMENT OF AORTA	Aortic	1	0	1
L221	REVISION OF PROSTHESIS OF THORACIC AORTA		0	0	0
L222	REVISION OF PROSTHESIS OF BIFURCATION OF AORTA	Aortic	1	1	2
L223	REVISION OF PROSTHESIS OF ABDOMINAL AORTA NEC	Aortic	1	1	2
L224	REMOVAL OF PROSTHESIS FROM AORTA	Aortic	1	0	1
L228	OS ATTENTION TO PROSTHESIS OF AORTA	Aortic	0	0	0
L229	US ATTENTION TO PROSTHESIS OF AORTA	Aortic	0	0	0
L231	PLASTIC REPAIR/AORTA AND END TO END ANAST.AORTA	Supra-renal etc.	7	9	16
L232	PLASTIC REPAIR OF AORTA USING SUBCLAVIAN FLAP	Supra-renal etc.	6	3	9
L233	PLASTIC REPAIR OF AORTA USING PATCH GRAFT	Supra-renal etc.	6	5	11
L234	RELEASE OF VASCULAR RING OF AORTA (PLASTIC REPAIR)	Supra-renal etc.	1	1	2
L235	REVISION OF PLASTIC REPAIR OF AORTA	Supra-renal etc.	0	1	1
L238	OTHER SPECIFIED PLASTIC REPAIR OF AORTA	Supra-renal etc.	1	2	3
L239	UNSPECIFIED PLASTIC REPAIR OF AORTA	Supra-renal etc.	0	1	1
L251	ENDARTERECTOMY OF AORTA AND PATCH REPAIR OF AORTA(OPEN OPS.)	Supra-renal etc.	0	1	1
L252	ENDARTERECTOMY OF AORTA NEC (OPEN OPS.)	Supra-renal etc.	0	0	0
L253	OPEN EMBOLECTOMY OF BIFURCATION OF AORTA	Reconstruction	0	4	4
L254	OPERATIONS ON AORTIC BODY (OPEN OPS.)	Aortic	17	22	39
L255	OPERATIONS ON AORTIC BODY		0	0	0
L258	OTHER SPECIFIED OPEN OPERATIONS ON AORTA	Aortic	2	5	7
L259	UNSPECIFIED OTHER OPEN OPERATIONS ON AORTA	Aortic	0	1	1
L261	PERCUTANEOUS TRANSLUMINAL BALLOON ANGIOPLASTY OF AORTA	Angioplasty	13	2	15
L262	PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF AORTA NEC	Angioplasty	10	1	11
L263	PERCUTANEOUS TRANSLUMINAL EMBOLECTOMY/BIFURCATION/AORTA	Angioplasty	0	0	0
L264	AORTOGRAPHY	Angiography	782	128	910
L268	OTHER SPECIFIED TRANSLUMINAL OPERATIONS ON AORTA	Angioplasty	128	14	142
L269	UNSPECIFIED TRANSLUMINAL OPERATIONS ON AORTA	Angioplasty	3	1	4
L291	REPLACEMENT OF CAROTID ARTERY USING GRAFT	Carotid	1	1	2
L292	INTRACRANIAL BYPASS TO CAROTID ARTERY		0	0	0
L293	BYPASS TO CAROTID ARTERY NEC	Carotid	5	1	6
L294	ENDARTERECTOMY/CAROTID ARTERY & PATCH REPAIR/CAROTID ARTERY	Carotid	249	19	268
L295	ENDARTERECTOMY OF CAROTID ARTERY NEC	Carotid	110	15	125
L298	OTHER SPECIFIED RECONSTRUCTION OF CAROTID ARTERY	Carotid	0	0	0
L299	UNSPECIFIED RECONSTRUCTION OF CAROTID ARTERY	Carotid	0	0	0
L301	REPAIR OF CAROTID ARTERY NEC (OPEN OPERATIONS)	Carotid	0	2	2

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
L302	LIGATION OF CAROTID ARTERY (OPEN OPERATIONS)	Carotid	2	5	7
L303	OPEN EMBOLECTOMY OF CAROTID ARTERY	Carotid	1	0	1
L304	OPERATIONS ON ANEURYSM CAROTID ARTERY	Carotid	8	8	16
L305	OPERATIONS ON CAROTID BODY	Carotid	4	0	4
L308	OTHER SPECIFIED OPEN OPERATIONS ON CAROTID ARTERY	Carotid	3	4	7
L309	UNSPECIFIED OTHER OPEN OPERATIONS ON CAROTID ARTERY	Carotid	0	0	0
L311	PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF CAROTID ARTERY	Carotid	62	6	68
L312	ARTERIOGRAPHY OF CAROTID ARTERY	Angiography	239	39	278
L318	OSPEC.TRANSLUMINAL OPERATIONS ON CAROTID ARTERY	Carotid	8	0	8
L319	UNSPEC.OTHER TRANSLUMINAL OPERATIONS ON CAROTID ARTERY	Carotid	0	0	0
L331	EXCISION OF ANEURYSM OF CEREBRAL ARTERY		0	1	1
L332	CLIPPING OF ANEURYSM OF CEREBRAL ARTERY		23	77	100
L333	LIGATION OF ANEURYSM OF CEREBRAL ARTERY NEC		0	0	0
L334	OBLITERATION OF ANEURYSM OF CEREBRAL ARTERY NEC		1	0	1
L338	OTHER SPECIFIED OPERATIONS ON ANEURYSM OF CEREBRAL ARTERY		1	0	1
L339	UNSPECIFIED OTHER OPERATIONS ON ANEURYSM OF CEREBRAL ARTERY		0	0	0
L341	RECONSTRUCTION OF CEREBRAL ARTERY		0	0	0
L342	ANASTOMOSIS OF CEREBRAL ARTERY		0	0	0
L343	OPEN EMBOLECTOMY OF CEREBRAL ARTERY		0	0	0
L344	OPEN EMBOLISATION OF CEREBRAL ARTERY		0	1	1
L348	OTHER SPECIFIED OPEN OPERATONS ON CEREBRAL ARTERY		0	0	0
L349	UNSPECIFIED OTHER OPEN OPERATIONS ON CEREBRAL ARTERY		0	0	0
L351	PERCUTANEOUS TRANSLUMINAL EMBOLISATION OF CEREBRAL ARTERY		6	5	11
L352	ARTERIOGRAPHY OF CEREBRAL ARTERY		24	5	29
L353	ARTERIOGRAPHY OF CEREBRAL ARTERY		0	0	0
L358	OTHER SPECIFIED TRANSLUMINAL OPERATIONS ON CEREBRAL ARTERY		2	3	5
L359	UNSPECIFIED OTHER TRANSLUMINAL OPERATIONS ON CEREBRAL ARTERY		0	0	0
L371	BYPASS OF SUBCLAVIAN ARTERY NEC (RECONSTRUCTION)	Upper limb	6	5	11
L372	ENDARTERECTOMY OF VERTEBRAL ARTERY (RECONSTRUCTION)		0	0	0
L373	ENDARTERECTOMY/SUBCLAVIAN ART.& PATCH REPAIR/SUBCLAVIAN ART.	Upper limb	0	1	1
L374	ENDARTERECTOMY OF SUBCLAVIAN ARTERY NEC (RECONSTRUCTION)	Upper limb	0	0	0
L378	OTHER SPECIFIED RECONSTRUCTION OF SUBCLAVIAN ARTERY	Upper limb	1	3	4
L379	UNSPECIFIED RECONSTRUCTION OF SUBCLAVIAN ARTERY	Upper limb	0	0	0
L381	REPAIR OF SUBCLAVIAN ARTERY NEC (OPEN OPS.)	Upper limb	1	12	13
L382	LIGATION OF SUBCLAVIAN ARTERY (OPEN OPS.)	Upper limb	0	2	2

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
L383	OPEN EMBOLECTOMY OF SUBCLAVIAN ARTERY	Upper limb	4	83	87
L384	OPERATIONS ON ANEURYSM OF SUBCLAVIAN ARTERY	Upper limb	1	4	5
L388	OTHER SPECIFIED OPEN OPERATIONS ON SUBCLAVIAN ARTERY	Upper limb	1	3	4
L389	UNSPECIFIED OTHER OPEN OPERATIONS ON SUBCLAVIAN ARTERY	Upper limb	0	0	0
L391	PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF SUBCLAVIAN ARTERY	Angioplasty	42	14	56
L392	PERCUTANEOUS TRANSLUMINAL EMBOLECTOMY OF SUBCLAVIAN ARTERY	Angioplasty	0	5	5
L393	PERCUTANEOUS TRANSLUMINAL EMBOLISATION OF SUBCLAVIAN ARTERY	Angioplasty	3	4	7
L394	ARTERIOGRAPHY OF SUBCLAVIAN ARTERY (TRANSLUMINAL OPS.)	Angiography	57	25	82
L398	OTHER SPECIFIED TRANSLUMINAL OPERATIONS ON SUBCLAVIAN ARTERY	Angioplasty	0	1	1
L399	UNSPECIFIED TRANSLUMINAL OPERATIONS ON SUBCLAVIAN ARTERY	Angioplasty	0	0	0
L411	PLASTIC REPAIR/RENAL ARTERY & END TO END ANAST/RENAL ARTERY	Supra-renal etc.	0	0	0
L412	BYPASS OF RENAL ARTERY (RECONSTRUCTION)	Supra-renal etc.	0	0	0
L413	REPLANTATION OF RENAL ARTERY (RECONSTRUCTION)	Supra-renal etc.	0	0	0
L414	ENDARTERECTOMY OF RENAL ARTERY (RECONSTRUCTION)	Supra-renal etc.	0	0	0
L415	TRANSLOCATION OF BRANCH OF RENAL ARTERY (RECONSTRUCTION)	Supra-renal etc.	3	0	3
L418	OTHER SPECIFIED RECONSTRUCTION OF RENAL ARTERY	Supra-renal etc.	0	0	0
L419	UNSPECIFIED RECONSTRUCTION OF RENAL ARTERY	Supra-renal etc.	1	0	1
L421	OPEN EMBOLECTOMY OF RENAL ARTERY	Supra-renal etc.	0	0	0
L422	OPEN EMBOLISATION OF RENAL ARTERY	Supra-renal etc.	0	0	0
L423	LIGATION OF RENAL ARTERY	Supra-renal etc.	0	0	0
L424	OPERATIONS ON ANEURYSM OF RENAL ARTERY	Supra-renal etc.	0	0	0
L428	OTHER SPECIFIED OPEN OPERATIONS ON RENAL ARTERY	Supra-renal etc.	0	0	0
L429	UNSPECIFIED OTHER OPEN OPERATIONS ON RENAL ARTERY	Supra-renal etc.	0	0	0
L431	PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF RENAL ARTERY	Angioplasty	25	10	35
L432	PERCUTANEOUS TRANSLUMINAL EMBOLECTOMY OF RENAL ARTERY	Angioplasty	0	0	0
L433	PERCUTANEOUS TRANSLUMINAL EMBOLISATION OF RENAL ARTERY	Angioplasty	4	2	6
L434	ARTERIOGRAPHY OF RENAL ARTERY (TRANSLUMINAL OPS.)	Angiography	25	15	40
L438	OTHER SPECIFIED TRANSLUMINAL OPERATIONS ON RENAL ARTERY	Angioplasty	0	0	0
L439	UNSPECIFIED TRANSLUMINAL OPERATIONS ON RENAL ARTERY	Angioplasty	0	0	0
L451	BYPASS OF VISCERAL BRANCH OF ABDOMINAL AORTA NEC	Supra-renal etc.	0	1	1
L452	REPLANTATION OF VISCERAL BRANCH OF ABDOMINAL AORTA NEC	Supra-renal etc.	0	0	0
L453	ENDARTERECTOMY/VISCERAL BRANCH/ABDOMIN.AORTA & PATCH REPAIR	Supra-renal etc.	0	0	0
L454	ENDARTERECTOMY OF VISCERAL BRANCH OF ABDOMINAL AORTA NEC	Supra-renal etc.	0	0	0
L458	OTHER SPECIFIED RECONSTRUCT/OTH.VISCERAL BRANCH/ABDOM.AORTA	Supra-renal etc.	1	1	2
L459	UNSPECIFIED RECONSTRUCT/OTH.VISCERAL BRANCH/ABDOM.AORTA	Supra-renal etc.	0	0	0

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
L461	OPEN EMBOLECTOMY OF VISCERAL BRANCH OF ABDOMINAL AORTA NEC	Supra-renal etc.	0	2	2
L462	OPEN EMBOLISATION OF VISCERAL BRANCH OF ABDOMINAL AORTA NEC	Supra-renal etc.	0	0	0
L463	LIGATION OF VISCERAL BRANCH OF ABDOMINAL AORTA NEC	Supra-renal etc.	0	4	4
L464	OPERATIONS ON ANEURYSM VISCERAL BRANCH OF ABDOMINAL AORT NEC	Supra-renal etc.	0	0	0
L468	OTHER SPECIFIED OPEN OPS.OTHER VISCERAL BRANCH/ABDOM.AORTA	Supra-renal etc.	1	0	1
L469	UNSPEC.OTHER OPEN OPS.OTHER VISCERAL BRANCH/ABDOMINAL AORTA	Supra-renal etc.	0	0	0
L471	PERCUTAN.TRANSLUM.ANGIOPLASTY/VISCERAL BRANCH/ABDOM.AORT.NEC	Angioplasty	10	2	12
L472	PERCUTAN TRANSLUMNL EMBOLISATN VISCERAL BRNCH ABDO ART NEC	Angioplasty	1	2	3
L473	ARTERIOGRAPHY OF VISCERAL BRANCH OF ABDOMINAL AORTA NEC	Angiography	65	35	100
L474	ARTERIOGRAPHY OF VISCERAL BRANCH OF ABDOMINAL AORTA NEC	Angiography	0	0	0
L478	OTHER SPECIFIED TRANSLUM.OPS.OTH.VISCERAL BRANCH/ABDOM AORTA	Angioplasty	0	0	0
L479	UNSPECIFIED TRANSLUM.OPS.OTH.VISCERAL BRANCH/ABDOM.AORTA	Angioplasty	0	0	0
L481	EMERG.REPLACE/ANEURYSMAL COM.ILIAC ART.ANAST/AORT.COM.IL.ART	Aortic	0	1	1
L482	EMERG.REPLACE/ANEURYSMAL IL.ART.ANAST/AOTA.EXTERN.ILIAC ART.	Aortic	0	0	0
L483	EMERG.REPLACE/ANEURYSMAL ART/LEG.ANAST/AORTA.COMMON FEM.ART	Aortic	0	0	0
L484	EMERG.REPLACE/ANEURYSMAL ART/LEG.ANAST/AORTA.SUPER.FEM.ART	Aortic	0	0	0
L485	EMERG.REPLACE/ANEURYSMAL IL.ART.BY.ANAST/ILIAC ARTERY.IL.ART	Aortic	0	3	3
L486	EMERG.REPLACE/ANEURYSMAL ART/LEG.ANAST/ILIAC ARTERY.FEM.ART	Aortic	0	0	0
L488	OTHER SPECIFIED EMERGENCY REPLACE/ANEURYSMAL ILIAC ARTERY	Aortic	0	0	0
L489	UNSPECIFIED EMERGENCY REPLACE/ANEURYSMAL ILIAC ARTERY	Aortic	0	0	0
L491	REPLACE/ANEURYSMAL COM.ILIAC AER.ANAST/AORTA.COM.ILIAC NEC	Aortic	2	0	2
L492	REPLACE/ANEURYSMAL ILIAC ART.ANAST/AORTA.EXTERN.IL.ART.NEC	Aortic	2	0	2
L493	REPLACE/ANEURYSMAL ART/LEG.ANAST/AORTA.COMMON FEM.ART.NEC	Aortic	3	0	3
L494	REPLACE/ANEURYSMAL ART/LEG.ANAST/AORTA.SUPERFIC.FEM.ART.NEC	Aortic	1	0	1
L495	REPLACE/ANEURYSMAL ILIAC ART.BY ANAST/ILIAC ART.TO I.ART.NEC	Aortic	1	1	2
L496	REPLACE/ANEURYSMAL ART./LEG BY ANAST/ILIAC ART.TO FEM.ART	Aortic	3	2	5
L498	OTHER SPECIFIED REPLACEMENT OF ANEURYSMAL ILIAC ARTERY	Aortic	0	0	0
L499	UNSPECIFIED OTHER REPLACEMENT OF ANEURYSMAL ILIAC ARTERY	Aortic	1	0	1
L501	EMERG.BYPASS/COM.ILIAC ART.ANAST/AORTA/COM.ILIAC ART.NEC	Aortic	1	0	1
L502	EMERG.BYPASS/ILIAC ART.ANAST/AORTA TO EXTERN.ILIAC ART.NEC	Aortic	0	0	0
L503	EMERG.BYPASS/ART/LEG BY ANAST/AORTA TO COM.FEMORAL ART.NEC	Aortic	1	3	4
L504	EMERG.BYPASS/ART/LEG BY ANAST/AORTA TO DEEP FEMORAL ART.NEC	Aortic	0	0	0
L505	EMERG.BYPASS/ILIAC ART.BY ANAST/ILIAC ART.ILIAC ART.NEC	Reconstruction	0	0	0
L506	EMERG.BYPASS/ART/LEG BY ANAST/ILIAC ART.TO FEMORAL ART.NEC	Reconstruction	0	3	3
L508	OTHER SPECIFIED EMERGENCY BYPASS OF ILIAC ARTERY	Aortic	2	2	4

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
L509	UNSPECIFIED OTHER EMERGENCY BYPASS OF ILIAC ARTERY	Aortic	0	1	1
L511	BYPASS/COM ILIAC ART BY ANAST/AORTA TO COM.ILIAC ART.NEC	Aortic	2	2	4
L512	BYPASS/ILIAC ART.BY ANAST/AORTA TO EXTERNAL ILIAC ART.NEC	Aortic	1	1	2
L513	BYPASS/ART/LEG BY ANAST/AORTA TO COMMON FEMORAL ART.NEC	Aortic	50	13	63
L514	BYPASS/ART/LEG BY ANAST/AORTA TO DEEP FEMORAL ART.NEC	Aortic	13	3	16
L515	BYPASS/ILIAC ART.BY ANAST/ILIAC ART.TO ILIAC ART.NEC	Reconstruction	2	0	2
L516	BYPASS/ART/LEG BY ANAST/ILIAC ART.TO FEMORAL ART.NEC	Reconstruction	75	22	97
L518	OTHER SPECIFIED BYPASS OF ILIAC ARTERY	Aortic	26	13	39
L519	UNSPECIFIED OTHER BYPASS OF ILIAC ARTERY	Aortic	1	0	1
L521	ENDARTERECTOMY/ILIAC ARTERY & PATCH REPAIR/ILIAC ARTERY	Reconstruction	2	0	2
L522	ENDARTERECTOMY OF ILIAC ARTERY NEC (RECONSTRUCTION)	Reconstruction	1	0	1
L528	OTHER SPECIFIED RECONSTRUCTION OF ILIAC ARTERY	Reconstruction	0	0	0
L529	UNSPECIFIED RECONSTRUCTION OF ILIAC ARTERY	Reconstruction	0	0	0
L531	REPAIR OF ILIAC ARTERY NEC	Reconstruction	2	5	7
L532	OPEN EMBOLECTOMY OF ILIAC ARTERY	Reconstruction	2	10	12
L533	OPERATIONS ON ANEURYSM OF ILIAC ARTERY NEC	Aortic	2	4	6
L538	OTHER SPECIFIED OTHER OPEN OPERATIONS ON ILIAC ARTERY	Reconstruction	0	1	1
L539	UNSPECIFIED OTHER OPEN OPERATIONS ON ILIAC ARTERY	Reconstruction	0	0	0
L541	PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF COMMON ILIAC ARTERY	Angioplasty	669	84	753
L542	PERCUTANEOUS TRANSLUMINAL EMBOLECTOMY OF COMMON ILIAC ARTERY	Angioplasty	0	5	5
L543	ARTERIOGRAPHY OF ILIAC ARTERY	Angiography	94	13	107
L548	OTHER SPECIFIED TRANSLUMINAL OPERATIONS ON ILIAC ARTERY	Angioplasty	22	2	24
L549	UNSPECIFIED TRANSLUMINAL OPERATIONS ON ILIAC ARTERY	Angioplasty	1	0	1
L561	EMERG.REP/ANEURYSMAL COM.FEM.ART.ANAST/FEM.ART.FEM.ART.	Reconstruction	0	3	3
L562	EMERG.REP/ANEURYSMAL FEM ART.ANAST.FEM.ART.POP.ART.PROST	Reconstruction	2	0	2
L563	EMERG.REP/ANEURYS.FEM.ART.ANAST/FEM.ART.POP.ART.VEIN GRAFT	Reconstruction	2	1	3
L564	EMERG.REP/ANEURYSMAL FEM.ART.ANAST/FEM.ART.TIB.ART.PROSTHES.	Femoro-distal	0	0	0
L565	EMERG.REP/ANEURYSMAL FEM.ART.ANAST/FEM.ART.TIB.ART.VEIN GRAF	Femoro-distal	0	2	2
L566	EMERG.REP/ANEURYSMAL FEM ART.ANAST/FEM.ART.PER.ART.PROST	Femoro-distal	0	0	0
L567	EMERG.REP/ANEURYSMAL FEM.ART.ANAST/FEM.ART.PER.ART.VEIN GRAF	Femoro-distal	0	0	0
L568	OTHER SPECIFIED EMERG.REPLACEMENT/ANEURYSMAL FEMORAL ARTERY	Reconstruction	0	1	1
L569	UNSPECIFIED EMERG.REPLACEMENT/ANEURYSMAL FEMORAL ARTERY	Reconstruction	1	2	3
L571	REPLACE/ANEURYSMAL FEM ART.BY ANAST/FEM.ART.TO FEMOR ART.NEC	Reconstruction	9	1	10
L572	REP/ANEURYSMAL FEM.ART.ANAST/FEM ART.POP ART.PROST NEC	Reconstruction	5	1	6
L573	REP/ANEURYSMAL FEM ART.ANAST/FEM ART.POP ART.VEIN GRAFT NEC	Reconstruction	14	3	17

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
L574	REP/ANEURYSMAL FEM ART.ANAST/FEM.ART.TIB ART.US.PROST NEC	Femoro-distal	0	0	0
L575	REP/ANEURYSMAL FEM ART.ANAST/FEM ART.TIB ART.VEIN GRAFT NEC	Femoro-distal	1	1	2
L576	REP/ANEURYSMAL FEM.ART.ANAST/FEM.ART.PER.ART.USE.PROST.NEC	Femoro-distal	0	0	0
L577	REP/ANEURYSMAL FEM.ART BY ANAST/FEM.ART TO PER.ART USE VEIN	Femoro-distal	3	2	5
L578	OTHER SPECIFIED REPLACEMENT OF ANEURYSMAL FEMORAL ARTERY	Reconstruction	0	2	2
L579	UNSPECIFIED OTHER REPLACEMENT OF ANEURYSMAL FEMORAL ARTERY	Reconstruction	7	4	11
L581	EMERG.BYPASS/FEM.ART BY ANAST/FEM.ART TO FEM ART.NEC	Reconstruction	2	7	9
L582	EMERG.BYPASS/FEM.ART BY ANAST/FEM.ART TO POP ART.PROST NEC	Reconstruction	0	6	6
L583	EMERG.BYPASS/FEM.ART.ANAST/FEM.ART TO POP ART.VEIN GRAFT NEC	Reconstruction	2	8	10
L584	EMERG.BY/FEM.ART.ANAST/FEM.ART TO TIB ART.USE.PROST.NEC	Femoro-distal	1	0	1
L585	EMERG.BY/FEM.ART.ANAST/FEM ART TO TIB ART.VEIN GRAFT NEC	Femoro-distal	0	4	4
L586	EMERG.BY/FEM.ART.ANAST/FEM.ART TO PER.ART.PROST NEC	Femoro-distal	0	0	0
L587	EMERG BY/FEM ART.ANAST/FEM ART.TO PER ART.VEIN GRAFT NEC	Femoro-distal	2	1	3
L588	OTHER SPECIFIED EMERGENCY BYPASS OF FEMORAL ARTERY	Reconstruction	0	2	2
L589	UNSPECIFIED OTHER EMERGENCY BYPASS OF FEMORAL ARTERY	Reconstruction	1	0	1
L591	BYPASS/FEM.ART BY ANAST/FEMORAL ART.TO FEMORAL ART.NEC	Reconstruction	98	42	140
L592	BYPASS/FEM.ART BY ANAST/FEM ART.POPLITEAL ART.USE.PROST.NEC	Reconstruction	141	54	195
L593	BYPASS/FEM.ART.ANAST/FEM.ART.POPLIT.ART.USE.VEIN GRAFT NEC	Reconstruction	300	108	408
L594	BYPASS/FEM.ART.ANAST/FEM.ART.TO TIB.ART.USE.PROST.NEC	Femoro-distal	25	25	50
L595	BYPASS/FEM.ART.ANAST/FEM ART.TO TIB ART.USE.VEIN GRAFT NEC	Femoro-distal	62	45	107
L596	BYPASS/FEM.ART BY ANAST/FEM.ART.TO PER.ART.USE.PROST.NEC	Femoro-distal	5	2	7
L597	BYPASS/FEM ART.BY ANAST/FEM ART.PER ART.USE.VEIN GRAFT NEC	Femoro-distal	20	10	30
L598	OTHER SPECIFIED BYPASS OF FEMORAL ARTERY	Reconstruction	20	7	27
L599	UNSPECIFIED OTHER BYPASS OF FEMORAL ARTERY	Reconstruction	6	8	14
L601	ENDARTERECTOMY/FEMORAL ARTERY & PATCH REPAIR/FEMORAL ARTERY	Reconstruction	35	11	46
L602	ENDARTERECTOMY OF FEMORAL ARTERY NEC	Reconstruction	21	9	30
L603	PROFUNDOPLASTY/FEMORAL ARTERY & PATCH REPAIR/DEEP FEM.ARTERY	Reconstruction	9	5	14
L604	PROFUNDOPLASTY OF FEMORAL ARTERY NEC	Reconstruction	6	0	6
L608	OTHER SPECIFIED RECONSTRUCTION OF FEMORAL ARTERY	Reconstruction	1	2	3
L609	UNSPECIFIED RECONSTRUCTION OF FEMORAL ARTERY	Reconstruction	0	0	0
L621	REPAIR OF FEMORAL ARTERY NEC (OPEN OPS.)	Reconstruction	6	9	15
L622	OPEN EMBOLECTOMY OF FEMORAL ARTERY (OPEN OPS.)	Reconstruction	13	218	231
L623	LIGATION OF ANEURYSM OF POPLITEAL ARTERY (OPEN OPS.)	Reconstruction	2	1	3
L624	OPERATIONS ON ANEURYSM OF FEMORAL ARTERY NEC	Reconstruction	16	14	30
L628	OTHER SPECIFIED OTHER OPEN OPERATIONS ON FEMORAL ARTERY	Reconstruction	15	9	24

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
L629	UNSPECIFIED OTHER OPEN OPERATIONS ON FEMORAL ARTERY	Reconstruction	0	1	1
L631	PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF FEMORAL ARTERY	Angioplasty	1757	348	2105
L632	PERCUTANEOUS TRANSLUMINAL EMBOLECTOMY OF FEMORAL ARTERY	Angioplasty	9	24	33
L633	PERCUTANEOUS TRANSLUMINAL EMBOLISATION OF FEMORAL ARTERY	Angioplasty	11	9	20
L634	ARTERIOGRAPHY OF FEMORAL ARTERY	Angiography	2523	506	3029
L638	OTHER SPECIFIED TRANSLUMINAL PROCS.ON FEMORAL ARTERY	Angioplasty	15	17	32
L639	UNSPECIFIED OTHER TRANSLUMINAL PROCS.ON FEMORAL ARTERY	Angioplasty	1	1	2
L651	REVISION OF RECONSTRUCTION INVOLVING AORTA	Supra-renal etc.	1	6	7
L652	REVISION OF RECONSTRUCTION INVOLVING ILIAC ARTERY	Aortic	2	3	5
L653	REVISION OF RECONSTRUCTION INVOLVING FEMORAL ARTERY	Reconstruction	15	20	35
L658	OTHER SPECIFIED REVISION OF RECONSTRUCTION OF ARTERY	Reconstruction	1	2	3
L659	UNSPECIFIED REVISION OF RECONSTRUCTION OF ARTERY	Reconstruction	1	0	1
L671	BIOPSY OF ARTERY NEC (OTHER ARTERY)		188	203	391
L678	OTHER SPECIFIED EXCISION OF OTHER ARTERY		4	4	8
L679	UNSPECIFIED EXCISION OF OTHER ARTERY		2	2	4
L681	ENDARTERECTOMY AND PATCH REPAIR OF ARTERY NEC	Reconstruction	0	0	0
L682	ENDARTERECTOMY NEC (REPAIR OF OTHER ARTERY)	Reconstruction	0	0	0
L683	REPAIR OF ARTERY USING PROSTHESIS NEC (OTHER ARTERY)	Reconstruction	1	0	1
L684	REPAIR OF ARTERY USING VEIN GRAFT NEC (OTHER ARTERY)	Reconstruction	4	10	14
L688	OTHER SPECIFIED REPAIR OF OTHER ARTERY	Reconstruction	4	36	40
L689	UNSPECIFIED REPAIR OF OTHER ARTERY	Reconstruction	3	35	38
L701	OPEN EMBOLECTOMY OF ARTERY NEC (OTHER ARTERY)	Reconstruction	3	9	12
L702	OPEN EMBOLISATION OF ARTERY NEC (OTHER ARTERY)		1	2	3
L703	LIGATION OF ARTERY NEC (OPEN OPS.ON OTHER ARTERY)		4	31	35
L704	OPEN CANNULATION OF ARTERY NEC (OTHER ARTERY)		0	6	6
L705	OPERATIONS ON ANEURYSM OF ARTERY NEC	Reconstruction	9	0	9
L708	OTHER SPECIFIED OTHER OPEN OPERATIONS ON OTHER ARTERY	Reconstruction	5	9	14
L709	UNSPECIFIED OTHER OPEN OPERATIONS ON OTHER ARTERY	Reconstruction	0	0	0
L711	PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF ARTERY NEC	Angioplasty	34	4	38
L712	PERCUTANEOUS TRANSLUMINAL EMBOLECTOMY OF ARTERY NEC	Angioplasty	1	3	4
L713	PERCUTANEOUS TRANSLUMINAL EMBOLISATION OF ARTERY NEC	Angioplasty	3	3	6
L714	PERCUTANEOUS TRANSLUMINAL CANNULATION OF ARTERY NEC (OTHER)	Angioplasty	2	3	5
L715	PERCUTANEOUS TRANSLUMINAL DILATION OF ARTERY NEC	Angioplasty	1	0	1
L718	OTHER SPECIFIED THERAPEUTIC TRANSLUMINAL OPS.ON OTHER ART.	Angioplasty	0	6	6
L719	UNSPECIFIED THERAPEUTIC TRANSLUMINAL OPS.ON OTHER ARTERY	Angioplasty	0	1	1

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
L721	ARTERIOGRAPHY NEC	Angiography	316	57	373
L722	MONITORING/ARTERIAL PRESSURE(DIAG.TRANSLUM.OPS.ON OTHER ART)		2	0	2
L723	PERCUTANEOUS TRANSLUMINAL ANGIOSCOPY NEC		0	0	0
L728	OTHER SPECIFIED DIAG.TRANSLUM.OPS.ON OTHER ARTERY		1	0	1
L729	UNSPECIFIED DIAG.TRANSLUM.OPERATIONS ON OTHER ARTERY		0	0	0
L741	INSERTION OF ARTERIOVENOUS PROSTHESIS (SHUNT)		54	13	67
L742	CREATION OF ARTERIOVENOUS FISTULA NEC (SHUNT)		368	57	425
L743	ATTENTION TO ARTERIOVENOUS SHUNT		27	22	49
L748	OTHER SPECIFIED ARTERIOVENOUS SHUNT		1	1	2
L749	UNSPECIFIED ARTERIOVENOUS SHUNT		0	0	0
L751	EXCISION OF CONGENITAL ARTERIOVENOUS MALFORMATION		7	0	7
L752	REPAIR OF ACQUIRED ARTERIOVENOUS FISTULA		38	8	46
L753	EMBOLISATION OF ARTERIOVENOUS ABNORMALITY		8	4	12
L758	OTHER SPECIFIED ARTERIOVENOUS OPERATIONS		4	0	4
L759	UNSPECIFIED ARTERIOVENOUS OPERATIONS		0	0	0
L771	CREATION/PORTOCAVAL SHUNT (CONNECT OF VENA CAVA)		0	0	0
L772	CREATION OF MESOCAVAL SHUNT (CONNECT OF VENA CAVA)		0	0	0
L773	CREATION OF PORTOSYSTEMIC SHUNT NEC (CONNECT OF VENA CAVA)		0	1	1
L774	CREATION OF DISTAL SPLENORENAL SHUNT (CONNECT OF VENA CAVA)		0	0	0
L775	CREATION OF PROXIMAL SPLENORENAL SHUNT(CONNECT OF VENA CAVA)		0	0	0
L778	OTHER SPECIFIED CONNECTION/VENA CAVA OR BRANCH OF VENA CAVA		0	0	0
L779	UNSPECIFIED CONNECTION/VENA CAVA OR BRANCH OF VENA CAVA		0	0	0
L791	INSERTION OF FILTER INTO VENA CAVA (OTHER OPS.)		2	2	4
L792	PLICATION OF VENA CAVA (OTHER OPS.)		0	0	0
L798	OTHER SPECIFIED OPERATIONS ON VENA CAVA		3	0	3
L799	UNSPECIFIED OTHER OPERTATIONS ON VENA CAVA		0	0	0
L811	CREATION OF PERITOVENOUS SHUNT		3	0	3
L812	BYPASS OPERATIONS FOR PRIAPISM		0	0	0
L818	OTHER SPECIFIED BYPASS OPERATIONS ON VEIN	Reconstruction	2	1	3
L819	UNSPECIFIED OTHER BYPASS OPERATIONS ON VEIN	Reconstruction	0	0	0
L821	TRANSPOSITION OF VALVE OF VEIN		0	0	0
L822	INTERPOSITION OF VALVE OF VEIN		0	0	0
L828	OTHER SPECIFIED REPAIR OF VALVE OF VEIN		0	0	0
L829	UNSPECIFIED REPAIR OF VALVE OF VEIN		0	0	0
L831	CROSSOVER GRAFT OF SAPHENOUS VEIN(OPS.FOR VEN.INSUFFIC.)	Reconstruction	1	0	1

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
L832	SUBFASCIAL LIGATION/PERFORATING VEIN/LEG (OPS.FOR INSUFFIC.)	VVs	47	2	49
L838	OTHER SPECIFIED OPERATIONS FOR VENOUS INSUFFICIENCY		0	1	1
L839	UNSPECIFIED OTHER OPERATIONS FOR VENOUS INSUFFICIENCY		0	0	0
L851	LIGATION OF LONG SAPHENOUS VEIN (LEG)	VVs	5997	34	6031
L852	LIGATION OF SHORT SAPHENOUS VEIN (LEG)	VVs	455	3	458
L853	LIGATION OF RECURRENT VARICOSE VEIN OF LEG	VVs	423	3	426
L858	OTHER SPECIFIED LIGATION OF VARICOSE VEIN OF LEG	VVs	110	1	111
L859	UNSPECIFIED LIGATION OF VARICOSE VEIN OF LEG	VVs	258	1	259
L861	INJECTION OF SCLEROSING SUBSTANCE INTO VARICOSE VEIN OF LEG		105	2	107
L868	OTHER SPECIFIED INJECTION INTO VARICOSE VEIN OF LEG		0	0	0
L869	UNSPECIFIED INJECTION INTO VARICOSE VEIN OF LEG		8	0	8
L871	STRIPPING OF LONG SAPHENOUS VEIN (VARICOSE)	VVs	276	9	285
L872	STRIPPING OF SHORT SAPHENOUS VEIN (VARICOSE)	VVs	11	0	11
L873	STRIPPING OF VARICOSE VEIN OF LEG NEC	VVs	35	3	38
L874	AVULSION OF VARICOSE VEIN OF LEG	VVs	2321	17	2338
L875	LOCAL EXCISION OF VARICOSE VEIN OF LEG	VVs	18	2	20
L876	INCISION OF VARICOSE VEIN OF LEG	VVs	2	0	2
L878	OS OPERATIONS ON VARICOSE VEIN OF LEG	VVs	13	2	15
L879	UNSPECIFIED OTHERR OPERATIONS ON VARICOSE VEIN OF LEG	VVs	24	0	24
L891	OPERATIONS ON JUGULAR BODY (SPECIFIED VEIN)		0	0	0
L892	OPERATIONS ON PULMONARY VEIN (SPECIFIED VEIN)		0	0	0
L898	OTHER SPECIFIED OPERATIONS ON OTHER SPECIFIED VEIN	VVs	0	0	0
L899	UNSPECIFIED OPERATIONS ON OTHER SPECIFIED VEIN	VVs	0	0	0
L901	OPEN THROMBECTOMY OF VEIN OF UPPER LIMB	Reconstruction	1	0	1
L902	OPEN THROMBECTOMY OF VEIN OF LOWER LIMB	Reconstruction	1	1	2
L908	OTHER SPECIFIED OPEN REMOVAL OF THROMBUS FROM VEIN	Reconstruction	1	0	1
L909	UNSPECIFIED OPEN REMOVAL OF THROMBUS FROM VEIN	Reconstruction	0	0	0
L911	OPEN INSERTION/CENTRAL VENOUS CATHETER (VEIN RELATED OPS.)		48	74	122
L912	INSERTION/CENTRAL VENOUS CATHETER NEC (VEIN RELATED OPS.)		24	161	185
L913	ATTENTION TO CENTRAL VENOUS CATHETER (VEIN RELATED OPS.)		29	24	53
L918	OTHER SPECIFIED VEIN RELATED OPERATIONS	VVs	12	11	23
L919	UNSPECIFIED OTHER VEIN RELATED OPERATIONS	VVs	0	0	0
L931	EXCISION OF VEIN NEC (OPEN OPS.)	VVs	5	2	7
L932	LIGATION OF VEIN NEC (OPEN OPS.)	VVs	0	0	0
L933	LIGATION OF VEIN NEC	VVs	16	26	42

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
L934	OPEN CANNULATION OF VEIN		1	2	3
L938	OTHER SPECIFIED OPEN OPERATIONS ON VEIN		6	2	8
L939	UNSPECIFIED OTHER OPEN OPERATIONS ON VEIN		0	0	0
L941	PERCUTANEOUS TRANSLUMINAL EMBOLISATION OF VEIN	Angioplasty	2	7	9
L942	PERCUTANEOUS TRANSLUMINAL CANNULATION OF VEIN	Angioplasty	3	8	11
L948	OTHER SPECIFIED THERAPEUTIC TRANSLUMINAL OPS.ON VEIN	Angioplasty	2	4	6
L949	UNSPECIFIED THERAPEUTIC TRANSLUMINAL OPS.ON VEIN	Angioplasty	0	0	0
L951	VENOGRAPHY (DIAGNOSTIC TRANSLUMINAL OPERATIONS ON VEIN)		101	3843	3944
L958	OTHER SPECIFIED DIAGNOSTIC TRANSLUMINAL OPERATIONS ON VEIN	Angioplasty	0	2	2
L959	UNSPECIFIED DIAGNOSTIC TRANSLUMINAL OPERATIONS ON VEIN	Angioplasty	0	1	1
L971	REVASCULARISATION FOR IMPOTENCE (OPS.ON BLOOD VESSEL)		0	0	0
L972	PEROPERATIVE ANGIOPLASTY (OPS.ON BLOOD VESSEL)	Reconstruction	2	2	4
L973	ISOLATED LIMB PERFUSION (OPS.ON BLOOD VESSEL)		105	0	105
L974	OPERATIONS ON ARTERY NEC	Reconstruction	2	2	4
L975	OPERATIONS ON VEIN NEC	VVs	2	1	3
L978	OTHER SPECIFIED OPERATIONS ON BLOOD VESSEL		4	1	5
L979	UNSPECIFIED OTHER OPERATIONS ON BLOOD VESSEL		1	0	1
X093	AMPUTATION OF LEG ABOVE KNEE	Major amp	115	397	512
X094	AMPUTATION OF LEG THROUGH KNEE	Major amp	23	50	73
X095	AMPUTATION OF LEG BELOW KNEE	Major amp	180	337	517
X098	OTHER SPECIFIED AMPUTATION OF LEG	Major amp	1	1	2
X099	UNSPECIFIED AMPUTATION OF LEG	Major amp	0	1	1
X101	AMPUTATION OF FOOT THROUGH ANKLE	Major amp	3	5	8
X102	DISARTICULATION OF TARSAL BONES	Minor amp	1	0	1
X103	DISARTICULATION OF METATARSAL BONES	Minor amp	6	0	6
X104	AMPUTATION THROUGH METATARSAL BONES	Minor amp	21	20	41
X108	OTHER SPECIFIED AMPUTATION OF FOOT	Minor amp	2	7	9
X109	UNSPECIFIED AMPUTATION OF FOOT	Minor amp	2	3	5
X111	AMPUTATION OF GREAT TOE	Minor amp	73	91	164
X112	AMPUTATION OF PHALANX OF TOE	Minor amp	146	36	182
X113	PROXIMAL HEMIPHALANGECTOMY OF TOE	Minor amp	0	0	0
X118	OTHER SPECIFIED AMPUTATION OF TOE	Minor amp	142	72	214
X119	UNSPECIFIED AMPUTATION OF TOE	Minor amp	276	119	395
X121	REAMPUTATION AT HIGHER LEVEL	Major amp	22	20	42
X122	EXCISION OF LESION OF AMPUTATION STUMP	Minor amp	14	2	16

continued

TABLE 70 contd

OPCS	Text	Casemix group	Elective	Emergency	Total
X123	SHORTENING OF LENGTH OF AMPUTATION STUMP	Major amp	13	8	21
X124	REVISION OF COVERAGE OF AMPUTATION STUMP	Minor amp	51	22	73
X125	DRAINAGE OF AMPUTATION STUMP	Minor amp	0	3	3
X128	OTHER SPECIFIED OPERATIONS ON AMPUTATION STUMP	Minor amp	44	135	179
X129	UNSPECIFIED OPERATIONS ON AMPUTATION STUMP	Minor amp	1	2	3

Appendix 2

Search strategies

Search strategy for volume–outcome review

The key words used in the searches of the databases were as follows.

1. exp Vascular surgical procedures/ut [Utilization]
2. exp Endarterectomy/ut [Utilization]
3. peripheral vascular.mp. [mp=title, abstract, registry number word, mesh subject heading]
4. exp Peripheral vascular diseases/
5. exp Carotid arteries/
6. exp Carotid artery diseases/
7. (surgeon volume or case volume or hospital volume).mp. [mp=title, abstract, registry number word, mesh subject heading]
8. (high volume or low volume).mp. [mp=title, abstract, registry number word, mesh subject heading]
9. ut.fs
10. exp Physician's practice patterns/
11. exp Health services misuse/
12. exp Utilization review/
13. utili#ation.mp [mp= title, abstract, registry number word, mesh subject heading]
16. 1 or 2 or 3 or 4 or 5 or 6
18. 16 and 17
19. limit 18 to (english language and yr=1986-1997)
21. vascular surg$.mp [mp= title, abstract, registry number word, mesh subject heading]
22. 16 or 21
23. 7 or 8 or 9 or 10 or 11 or 12 or 13
24. 22 and 23
25. limit 24 to (english language and yr=1986-1997)

Search strategy for thrombolysis review

The keywords used in the searches of the databases were as follows.

1. FIBRINOLYTIC-THERAPY"/ all subheadings
2. STREPTOKINASE
3. UROKINASE
4. "TISSUE PLASMINOGEN-ACTIVATOR"/ all subheadings
5. 1 or 2 or 3 or 4
6. ISCHEM*
7. ISHCHAEM*
8. ISCHEM* or ISCHAEM*
9. 5 and 8
10. LA = "ENGLISH"
11. 9 and (LA = "ENGLISH")
12. LIMB
13. LIMBS
14. LEG
15. LEGS
16. EXTREMIT*
17. LIMB or LIMBS or LEG or LEGS or EXTREMIT*
18. 11 and 17
19. TRIAL*
20. RANDOM*
21. CONTROL*
22. TRIAL* or RANDOM* or EXTREMIT*
23. MAJOR-CLINICAL-STUDY
24. 22 or 23
25. 18 and 24

Search strategy for economic review

The keywords used in the searches of the databases were as follows:

1. "PERIPHERAL-VASCULAR-DISEASES"/ all subheadings
2. LA = "ENGLISH"
3. #1 and (LA = "ENGLISH")
4. ECONOMICS
5. COSTS-AND-COST-ANALYSIS*
6. #4 or #5
7. #3 and #6
8. AORTIC-ANEURYSM*
9. #6 and #8
10. #7 or #9
11. "VASCULAR-SURGERY-ECONOMICS"
12. #10 or #11
13. "AORTIC-RUPTURE"
14. #6 and #13
15. #12 or #14
16. J-VASC-SURG
17. #6 and #16
18. #15 or #17
19. ISCHEMIA

20. "ISCHEMIA" IN MJME
21. #6 and #20
22. #18 or #21
23. LA = "ENGLISH"
24. #22 and (LA = "ENGLISH")
25. "ARTERIAL-OCCLUSIVE-DISEASES-ECONOMICS"
26. "CAROTID-ARTERY-DISEASES-ECONOMICS"
27. "INTERMITTENT-CLAUDICATION-ECONOMICS"
28. "ENDARTERECTOMY-ECONOMICS"
29. #24 or #25 or #26 or #27 or #28
30. PERIPHERAL
31. VASCULAR
32. PERIPHERAL
33. ARTERIAL
34. (PERIPHERAL VASCULAR) OR (PERIPHERAL ARTERIAL)
35. #6 and #34
36. #29 or #35
37. LA = "ENGLISH"
38. #36 and (LA = "ENGLISH")
39. "LEG-BLOOD-SUPPLY"
40. "SEMIN-VASC-SURG"
41. "EUR-J-VASC-ENDOVASC-SURG"
42. "EUR-J-VASC-SURG"
43. #39 or #40 or #41 or #42
44. #6 and #43
45. #38 or #44
46. LA = "ENGLISH"

*47 #45 and (LA = "ENGLISH")

Appendix 3

Data extraction table for studies of thrombolysis

TABLE 71

Study	Participants	Interventions	Baseline comparability	Results	Withdrawals	Comments
Graor *et al.*, 1994[106] STILE trial USA Multicentre trial Method of randomisation: Randomisation centre. Stratified by clinical centre Objective outcome: Composite clinical outcome event: ongoing or recurrent ischaemia; death or major amputation; life-threatening haemorrhage; perioperative complications (e.g. CVA, MI); renal failure requiring dialysis; anaesthesia-related complications; vascular complications (e.g. dissection, pseudoaneurysm, occlusion); wound complications Other endpoints: Clinical improvement; patency; duration of ischaemia; length of stay Setting and length of follow-up: Hospital; 6 months	No. participants: 393 Initial design for 1000 but enrolment stopped after first interim analysis Inclusion criteria: Patients with lower limb ischaemia < 6 months' duration caused by non-embolic arterial or graft occlusion Exclusion criteria: Embolic occlusion; infected graft occlusion; history of CVA or TIA or duodenal or gastric ulcer; diabetes; or thrombolysis contra-indications	I1: Surgical revascularisation (n = 144) I2a: rt-PA (n = 137) I2b: Urokinase (n = 112) Combined thrombolysis results n = 248	No statistically significant differences Post-protocol stratification by duration of ischaemic symptoms used after results showed this to be an indicator of treatment outcome	ITT analysis Surgery vs. thrombolysis: Composite clinical outcome Surgery 36.1% (n = 52) vs. 61.7% (n = 153); $p < 0.001$ Recurrent ischaemia Surgery 25.7% (n = 37) vs. 54% (n = 134); $p < 0.001$ Life-threatening haemorrhage I1: 0.7% (n = 1) I2: 5.6% (n = 14); $p = 0.014$ No significant differences in mortality, amputation or other outcomes at 1-month follow-up 6-month follow-up: Mortality/amputation rates ALI (< 14 days) Surgery group = 37.5% (n = 15/40) vs. 15.3% (n = 11/ 72); $p = 0.01$ Major amputation for ALI (< 14 days) Surgery 30% (12/ 40) vs. 11.1% (8/72); $p = 0.02$ This was reversed for ischaemia > 14 days Surgery 3% (3/101) vs. 12.1% (21/174); $p = 0.01$ Amputation-free survival at 6 months Surgery 70% and thrombolysis (90%); $p < 0.05$ rt-PA vs. urokinase No statistically significant difference	Total = 28 16 (11.1%) of surgical group 12 (4.8%) of thrombolysis group	Concludes that patients with acute ischaemia would benefit from thrombolysis while surgery should be used for those with chronic ischaemia There are relatively small numbers in the complication rates and no CI given

ALI, acute limb ischaemia

continued

TABLE 71 contd

Study	Participants	Interventions	Baseline comparability	Results	Withdrawals	Comments
Comerota *et al.*, 1996[111] USA Multicentre Method of randomisation: Randomisation centre. Stratified by clinical centre Objective outcome: Composite clinical outcome event: ongoing or recurrent ischaemia; death or major amputation; life-threatening haemorrhage; perioperative complications (e.g. CVA, MI); renal failure requiring dialysis; anaesthesia-related complications; vascular complications (e.g. dissection, pseudoaneurysm, occlusion); wound complications Other endpoints: Clinical improvement; patency; duration of ischaemia; length of stay Setting and length of follow-up: Hospital; 1 year	Report of subgroup of patients with occluded grafts from STILE trial[106] No. patients = 124 Inclusion criteria: Patients between 18 and 90 years with worsening limb ischaemia within past 6 months and angiographically documented non-embolic arterial or graft occlusion Exclusion criteria: Embolic occlusion; contraindication to thrombolysis or surgery; uncontrolled hypertension (systolic > 180 mmHg); pregnancy; infected bypass graft occlusions	I1: Surgery (n = 46) I2: Thrombolysis (n = 78) I2: Aggregated analysis of rt-PA and urokinase to give thrombolytic outcomes	No significant differences between the groups at baseline	ITT analysis Graft type: I1 and I2: prosthetic grafts tended to have increase 'major morbidity' compared with autogenous grafts; p = 0.04 Limb loss/major morbidity/mortality: I1 and I2: no statistically significant differences between the groups Ongoing/recurrent ischaemia: I1: 50% (n = 23) I2: 73% (n = 57); p = 0.01. Subgroup analysis Graft location: No difference in outcomes between surgery and thrombolysis for suprainguinal or infrainguinal locations Occluded popliteal vs. tibial bypass: I2: greater incidence of ongoing/recurrent ischaemia for tibial bypass at 1 month (p = 0.046) and 1 year (p = 0.001) Duration of ischaemia: 0–14 days: major amputation. I1: 48% (n = 11) I2: 20% (n = 7); p = 0.026 > 14 days: ongoing/recurrent ischaemia (1 year) I1: 41% (n = 9) I2: 81% (n = 34); p = 0.001 No other significant differences between I1 and I2	Not stated but analysis was by ITT analysis	Successful catheter placement for thrombolysis = 61%

continued

TABLE 71 contd

Study	Participants	Interventions	Baseline comparability	Results	Withdrawals	Comments
Weaver *et al.*, 1996[107] USA Multicentre trial Method of randomisation: Randomisation centre. Stratified by clinical centre Objective outcome: Composite clinical outcome event: ongoing or recurrent ischaemia; death or major amputation; life-threatening haemorrhage; perioperative complications (e.g. CVA, MI); renal failure requiring dialysis; anaesthesia-related complications; vascular complications (e.g. dissection, pseudoaneurysm, occlusion); wound complications Setting and length of follow-up: Hospital; 30 days, 6 months and 1 year	Reporting of subgroup of patients from the STILE Trial[106] with native artery occlusions No. randomised: 261 Inclusion criteria: As STILE trial Exclusion criteria: As STILE trial	I1: Surgery (n = 87) I2a: rt-PA (n = 84) I2b: Urokinase (n = 66) I2a and I2b outcomes combined to give thrombolysis outcomes	No significant differences between the groups at baseline	ITT analysis Mortality: No differences between the groups at 30 days, 6 months or 1 year Major amputation: 6 months I1: 0% I 2: 6.7% (n = 10); $p < 0.05$ 1 year I1: 0% I2: 10% (n = 15); $p < 0.05$ Subgroup analysis by location of occlusion Major amputation: Iliac-common femoral artery occlusions No difference between surgery and thrombolysis Superficial femoral-popliteal occlusions 6 months I1: 0% I2: 8.7% (n = 9); $p < 0.005$ 1 year I1: 0% I2: 13.5% (n = 14); $p = 0.001$ No other statistically significant differences between groups	Not reported but ITT analysis	Successful positioning of catheter for thrombolysis = 78%

continued

TABLE 71 contd

Study	Participants	Interventions	Baseline comparability	Results	Withdrawals	Comments
Ouriel *et al.*, 1996[81] TOPAS Phase I USA Multicentre Method of randomisation: Centralised randomisation centre; stratified by whether occlusion native artery or bypass graft Outcomes: Haemorrhage; mortality; amputation-free survival Length of follow-up: 30 days, 6 months and 1 year	No. randomised: 213 Inclusion criteria: Patients with acute lower limb peripheral artery occlusion of < 14 days' duration, thromboses or embolic aetiology Exclusion criteria: Contraindication to surgery or thrombolysis; systolic > 180; CVA within 6 months; TIA within 2 months; life expectancy < 1 year	I1a: 2000 IU/minute urokinase (n = 45) I1b: 4000 IU/minute urokinase (n = 49) I1c: 6000 IU/minute (n = 50) I2: Surgery (n = 59)	There were no significant differences between the groups at baseline Mean age: I1a: 66.2 ± 1.9 I1b: 62.2 ± 1.8 I1c: 62.5 ± 1.8 I2: 66.5 ± 1.8 p = 1.82 % Male: I1a: 70.7% I1b: 74.4% I1c: 76.1% I2: 66.5% p = 0.476	ITT analysis Severe or life-threatening haemorrhage: I1a: 6 I1b: 1 I1c: 8 I2: Not given. p = 0.031 for I1b vs. I1c Mortality: No statistically significant differences between the groups (p > 0.05) but "appeared to be least in 4000 IU group" Amputation-free survival: No statistically significant differences between the groups	I1a: 3 I1b: 3 I1c: 5 I2: 4	
Ouriel *et al.*, 1998[83] TOPAS Phase II USA and Europe Multicentre (n = 113) Method of randomisation: Randomisation centre; stratification by native artery or by-pass graft Objective outcome: Amputation-free survival at 6 months and 1 year; complications; ABPI Setting and length of follow-up: Hospital; 6 months and 1 year	No. participants: 548 Inclusion criteria: Acute thrombotic or embolic occlusion of < 14 days' duration Exclusion criteria: Contraindication for surgery or thrombolysis; pregnancy or chance of pregnancy	I1:Intra-arterial urokinase (n = 272) I2: Surgery (n = 272)	Sex (male): I1: 71% I2: 62%; p = 0.046 Rest pain: I1: 78% I2: 66%; p = 0.003 Hepatic/renal insufficiency: I1: 21% I2: 14%; p = 0.027 Other parameters were similar at baseline	ITT analysis Amputation-free survival: 6 months I1: 71.8% I2: 74.8%; p = 0.43 1 year I1: 65% I2: 69.9%; p = 0.23 Mortality, length of stay and ABPI: No statistically significant difference at 6 months or 1 year Major haemorrhagic complications: I1: 12.5% (n = 32) I2: 5.5% (n = 14); p = 0.005	Total of 33 patients post-randomisation	Very large number of participating centres. No breakdown of how many patients contributed by each centre

continued

TABLE 71 contd

Study	Participants	Interventions	Baseline comparability	Results	Withdrawals	Comments
Ouriel *et al.*, 1994[108] USA Single centre Method of randomisation: Computer-generated randomisation list Objective outcome: Mortality; limb salvage; major complications; length of stay Length of follow-up: Mean 20.5 months	No. participants: 119 randomised but 114 analysed Inclusion criteria: ALI < 7 days' duration Exclusion criteria: Contraindication for thrombolysis or operative revascularisation or arteriography; pregnancy	I1: Thrombolysis (intra-arterial) (n = 57) I2: Surgery (n = 57) Concurrent interventions: None	"Balanced" treatment groups but no p-values given	Kaplan-Meier analysis event-free survival 12 months Thrombolysis = 75% vs. 52% (p = 0.02) i.e. thrombolysis = 48% reduction in the 1-year risk of amputation or death Cumulative survival rate greater in thrombolysis group (84% vs. 58% at 1 year (p = 0.01)	Five post-randomisation	There was decreased mortality in the thrombolysis group and it should be used as the initial intervention for ALI
Nilsson *et al.*, 1992[109] Sweden Single centre Method of randomisation: Not stated Objective outcome: Successful revascularisation; complications; mortality Length of follow-up: 30 days	No. participants: 20 Inclusion criteria: Ischaemia of leg > 24 hours' duration but < 14 days Exclusion criteria: Systolic > 200; CVA within 6 months; surgery within previous 3 weeks; peptic ulcer; current treatment with anti-coagulants	I1: Surgery (thrombectomy) (n = 9) I2: Thrombolysis (intra-arterial rt-PA) (n = 11)	Sex: I1: 5 male, 4 female I2: 8 male, 3 female Duration of symptoms: I1: 2.9 days (range, 1–7) I2: 6.3 days (range, 1–14)	Successful revascularisation No significant difference between the two groups No incidence of mortality or major morbidity in either group	One from lysis group (I2)	Small study with samples size inadequate to detect any differences between the two treatments

ALI, acute limb ischaemia

continued

TABLE 71 contd

Study	Participants	Interventions	Baseline comparability	Results	Withdrawals	Comments
Berridge *et al.*, 1991[110] UK Single centre Method of randomisation: Not stated Outcomes: Radiological success; ABPI; limb salvage rates; complications Setting and length of follow-up: Hospital; 3 months	No. participants: 60 Inclusion criteria: Sudden onset or deterioration of peripheral limb ischaemia of < 30 days' duration sufficient to cause critical ischaemia Exclusion criteria: Embolic aetiology; child-bearing age; CVA within 2 months; contraindication to thrombolysis; arterial thrombus causing severe ischaemia with good run-off	I1: Intra-arterial streptokinase (n = 20) I2: Intra-arterial rt-PA (n = 20) I3: Intravenous rt-PA (n = 20)	No significant differences found at baseline	Radiological success: I1: Complete 16; partial 0; % total, 80% I2: Complete 17; partial 3; % total, 100% I3: Complete 6; partial 3; % total, 45% % total p = 0.04 3-month limb salvage rate: This did not achieve statistical significance I1: 60% (n = 12) I2: 75% (n = 15) I3: 50% (n = 10)	None stated	Small trial. Sample size not sufficient to detect differences between groups
Braithwaite *et al.*, 1997[80] UK Multicentre Method of randomisation: Not stated Outcomes: Duration of infusion; successful thrombolysis; complications; adjunctive procedures Setting and length of follow-up: Hospital; 3 months	No. participants = 100 Inclusion criteria: Patients > 18 years with sudden-onset unilateral leg ischaemia for whom thrombolysis considered as a treatment option; < 30 days' duration; native and graft occlusions eligible Exclusion criteria: Contraindication for thrombolysis due to CVA within 2 months; pregnancy; child-bearing age; patients with total (white leg) ischaemia	I1: High-dose intra-arterial rt-PA (3 x 5 mg over 30 minutes plus 3.5 mg/hour for 4 hours, then 0.5–1.0 mg/hour) (n = 49) I2: Conventional low-dose rt-PA (0.5–1.0 mg/h) (n = 44)	No significant differences found at baseline	Analysis excluded withdrawals 30-day limb salvage rate (% intention to treat): I1: 39 (78%) I2: 37 (74%); p = 0.58 Median duration of infusion: I1: 4 hours (range, 1–46) I2: 20 hours (range, 2–46); p < 0.0001 Complications: No significant differences between the groups Adjunctive procedures: I1: 26 I2: 16; p = 0.002	Seven in total I1: 1 I2: 6 Reasons: One duration of ischaemia > 30 days; one moribund; one collapsed graft; four thrombolysis infusions did not adhere to protocol	Study did not have sufficient power to detect differences in secondary endpoints or complication rates

Appendix 4

Standard gamble questionnaire booklet

Respondent Serial Number

STANDARD GAMBLE

RESPONSE BOOKLET

X

BACKGROUND INFORMATION.

1. **How old are you?** ____________ years

What sex are you?

Male ◯

Female ◯

2. **Are you in full-time education as a pupil/ student?**

Yes ◯

No ◯

3. **If "No", how old were you when you left full-time education?** _______ years

4. a) **Do you do any paid work as an employee or self-employed?**

Yes, full-time ◯

Yes , part-time ◯

No ◯

b) **If "NO", are you**

looking for work? ◯

permanently unable to work? ◯

wholly retired? ◯

looking after the home or family? ◯

other? ◯

If "other" please specify ____________________________________

---

3. What is (or was) the name and title of your main job?

Occupation ____

Industry ____

Here are some simple questions about your health in general. By ticking one answer in each group below, please indicate which statements best describe your own health state TODAY.

Please tick one

1. Mobility

I have no problems in walking about ○

I have some problems in walking about ○

I am confined to bed ○

2. Self-care

I have no problems with self-care ○

I have some problems washing or dressing myself ○

I am unable to wash or dress myself ○

3. Usual Activities

I have no problems with performing my usual activities *(e.g. work, study, housework, family or leisure activities)* ○

I have some problems with performing my usual activities ○

I am unable to perform my usual activities ○

4. Pain/Discomfort

I have no pain or discomfort ○

I have moderate pain or discomfort ○

I have extreme pain or discomfort ○

5. Anxiety/Depression

I am not anxious or depressed ○

I am moderately anxious or depressed ○

I am extremely anxious or depressed ○

STANDARD GAMBLE EXERCISE.

HEALTH STATE L

CHOICE "A"

You have no problems **walking** about You have no problems with **washing and dressing** You have no problems with your **usual activities** You have no **pain or discomfort** You are not **anxious or depressed**	Immediate Death

CHOICE "B"

100% CHANCE

L

You will be confined to **bed**

You will be dependent on the nursing staff for help with **using the toilet, dressing and washing**

You will be unable to carry out any of your **usual activities**

You will be experiencing very severe **pain** in the affected limb that will need morphine to control

You will feel extremely **anxious**, **depressed and frightened**

<u>HEALTH STATE L</u>

Please put a tick (✔) against all cases where you are **CONFIDENT** that you would **CHOOSE** the risky treatment in Choice A and a X against all cases where you are **CONFIDENT** that you would **REJECT** the treatment and accept the health state in Choice B.

Please put a = against the case where you think it would be most difficult to choose between having the treatment (Choice B).

THE CHANCES IN CHOICE A:

FOR OFFICE USE ONLY

Chance of Success	Chance of Failure	(✔, X or =)
100 in 100	0 in 100	
95 in 100	5 in 100	
90 in 100	10 in 100	
85 in 100	15 in 100	
80 in 100	20 in 100	
75 in 100	25 in 100	
70 in 100	30 in 100	
65 in 100	35 in 100	
60 in 100	40 in 100	
55 in 100	45 in 100	
50 in 100	50 in 100	
45 in 100	55 in 100	
40 in 100	60 in 100	
35 in 100	65 in 100	
30 in 100	70 in 100	
25 in 100	75 in 100	
20 in 100	80 in 100	
15 in 100	85 in 100	
10 in 100	90 in 100	
5 in 100	95 in 100	
0 in 100	100 in 100	
Would prefer Immediate Death		

HEALTH STATE M

CHOICE "A"

You have no problems **walking** about You have no problems with **washing and dressing** You have no problems with your **usual activities** You have no **pain or discomfort** You are not **anxious or depressed**	Immediate Death

CHOICE "B"

100% CHANCE

M

You will be able to **walk** a distance of up to a quarter of a mile with the use of an artificial leg

You will need occasional assistance with **washing and dressing**

You will have some problems with performing your **usual activities**

You will experience "**phantom pain**" in the amputated leg which will cause you some discomfort

You will feel **anxious and depressed** for some of the time

HEALTH STATE M

Please put a tick (✔) against all cases where you are **CONFIDENT** that you would **CHOOSE** the risky treatment in Choice A and a X against all cases where you are **CONFIDENT** that you would **REJECT** the treatment and accept the health state in Choice B.

Please put a = against the case where you think it would be most difficult to choose between having the treatment (Choice B).

THE CHANCES IN CHOICE A:

FOR OFFICE USE ONLY

Chance of Success	Chance of Failure	(✔, X or =)
100 in 100	0 in 100	
95 in 100	5 in 100	
90 in 100	10 in 100	
85 in 100	15 in 100	
80 in 100	20 in 100	
75 in 100	25 in 100	
70 in 100	30 in 100	
65 in 100	35 in 100	
60 in 100	40 in 100	
55 in 100	45 in 100	
50 in 100	50 in 100	
45 in 100	55 in 100	
40 in 100	60 in 100	
35 in 100	65 in 100	
30 in 100	70 in 100	
25 in 100	75 in 100	
20 in 100	80 in 100	
15 in 100	85 in 100	
10 in 100	90 in 100	
5 in 100	95 in 100	
0 in 100	100 in 100	
Would prefer Immediate Death		

HEALTH STATE N

CHOICE "A"

You have <u>no problems</u> **walking** about You have <u>no problems</u> with **washing and dressing** You have <u>no problems</u> with your **usual activities** You have <u>no</u> **pain or discomfort** You <u>are not</u> **anxious or depressed**	Immediate Death

CHOICE "B"

100% CHANCE

<u>N</u>

You will be <u>confined</u> to a **wheelchair**

You will <u>need assistance</u> with **dressing and washing**

You will have <u>a lot</u> of problems performing your **usual activities**

You will experience "**phantom pain**" in the amputated leg which will cause you <u>some discomfort</u>

You will feel **depressed and anxious**, <u>most</u> of the time

HEALTH STATE N
Please put a tick (✔) against all cases where you are **CONFIDENT** that you would **CHOOSE** the risky treatment in Choice A and a X against all cases where you are **CONFIDENT** that you would **REJECT** the treatment and accept the health state in Choice B.

Please put a = against the case where you think it would be most difficult to choose between having the treatment (Choice B).

THE CHANCES IN CHOICE A:

FOR OFFICE USE ONLY

Chance of Success	**Chance of Failure**	**(✔, X or =)**
100 in 100	0 in 100	
95 in 100	5 in 100	
90 in 100	10 in 100	
85 in 100	15 in 100	
80 in 100	20 in 100	
75 in 100	25 in 100	
70 in 100	30 in 100	
65 in 100	35 in 100	
60 in 100	40 in 100	
55 in 100	45 in 100	
50 in 100	50 in 100	
45 in 100	55 in 100	
40 in 100	60 in 100	
35 in 100	65 in 100	
30 in 100	70 in 100	
25 in 100	75 in 100	
20 in 100	80 in 100	
15 in 100	85 in 100	
10 in 100	90 in 100	
5 in 100	95 in 100	
0 in 100	100 in 100	
Would prefer Immediate Death		

HEALTH STATE P

CHOICE "A"

You have <u>no problems</u> **walking** about You have <u>no problems</u> with **washing and dressing** You have <u>no problems</u> with your **usual activities** You have <u>no</u> **pain or discomfort** You <u>are not</u> **anxious or depressed**	Immediate Death

CHOICE "B"

100% CHANCE

<u>P</u>

You will be limited to **walking** <u>short distances</u> (less than 50 yards) before having to stop due to cramp like pain in your legs. After 5 minutes the pain will have stopped and you will be able to carry on walking

You will need <u>occasional</u> assistance with **dressing and washing**

You will have <u>some</u> problems performing your **usual activities**

You will experience **cramp like pain** in your legs at night which will wake you up

You are likely to feel **anxious and depressed** <u>some</u> of the time

HEALTH STATE P

Please put a tick (✔) against all cases where you are **CONFIDENT** that you would **CHOOSE** the risky treatment in Choice A and a X against all cases where you are **CONFIDENT** that you would **REJECT** the treatment and accept the health state in Choice B.

Please put a = against the case where you think it would be most difficult to choose between having the treatment (Choice B).

THE CHANCES IN CHOICE A:

FOR OFFICE USE ONLY

Chance of Success	Chance of Failure	(✔, X or =)
100 in 100	0 in 100	
95 in 100	5 in 100	
90 in 100	10 in 100	
85 in 100	15 in 100	
80 in 100	20 in 100	
75 in 100	25 in 100	
70 in 100	30 in 100	
65 in 100	35 in 100	
60 in 100	40 in 100	
55 in 100	45 in 100	
50 in 100	50 in 100	
45 in 100	55 in 100	
40 in 100	60 in 100	
35 in 100	65 in 100	
30 in 100	70 in 100	
25 in 100	75 in 100	
20 in 100	80 in 100	
15 in 100	85 in 100	
10 in 100	90 in 100	
5 in 100	95 in 100	
0 in 100	100 in 100	
Would prefer Immediate Death		

HEALTH STATE Q

CHOICE "A"

You have no problems **walking** about You have no problems with **washing and dressing** You have no problems with your **usual activities** You have no **pain or discomfort** You are not **anxious or depressed**	Immediate Death

CHOICE "B"

100% CHANCE

Q

You will be able to walk up to a quarter of a mile before having to stop due to **cramp like pain** in your legs. After 5 minutes the pain will have stopped and you will be able to carry on walking

You will be able to **wash and dress** yourself without any help

You will have some problems performing your **usual activities**

You will not feel **anxious or depressed**

HEALTH STATE Q

Please put a tick (✔) against all cases where you are **CONFIDENT** that you would **CHOOSE** the risky treatment in Choice A and a X against all cases where you are **CONFIDENT** that you would **REJECT** the treatment and accept the health state in Choice B.

Please put a = against the case where you think it would be most difficult to choose between having the treatment (Choice B).

THE CHANCES IN CHOICE A:

FOR OFFICE USE ONLY

Chance of Success	**Chance of Failure**	**(✔, X or =)**
100 in 100	0 in 100	
95 in 100	5 in 100	
90 in 100	10 in 100	
85 in 100	15 in 100	
80 in 100	20 in 100	
75 in 100	25 in 100	
70 in 100	30 in 100	
65 in 100	35 in 100	
60 in 100	40 in 100	
55 in 100	45 in 100	
50 in 100	50 in 100	
45 in 100	55 in 100	
40 in 100	60 in 100	
35 in 100	65 in 100	
30 in 100	70 in 100	
25 in 100	75 in 100	
20 in 100	80 in 100	
15 in 100	85 in 100	
10 in 100	90 in 100	
5 in 100	95 in 100	
0 in 100	100 in 100	
Would prefer Immediate Death		

HEALTH STATE R

CHOICE "A"

You have no problems **walking** about You have no problems with **washing and dressing** You have no problems with your **usual activities** You have no **pain or discomfort** You are not **anxious or depressed**	Immediate Death

CHOICE "B"

100% CHANCE

R

You will be able to walk up to a quarter of a mile before having to stop due to **cramp like pain** in your legs. After 5 minutes the pain will have stopped and you will be able to carry on walking

You will be able to **wash and dress** yourself without any help

You will have some problems performing your **usual activities**

You are likely to have mild wound **pain** in your leg for which you will need to take paracetamol

You will feel **anxious and depressed** some of the time

<u>HEALTH STATE R</u>

Please put a tick (✔) against all cases where you are **CONFIDENT** that you would **CHOOSE** the risky treatment in Choice A and a X against all cases where you are **CONFIDENT** that you would **REJECT** the treatment and accept the health state in Choice B.

Please put a = against the case where you think it would be most difficult to choose between having the treatment (Choice B).

THE CHANCES IN CHOICE A:

FOR OFFICE USE ONLY

Chance of Success	Chance of Failure	(✔, X or =)
100 in 100	0 in 100	
95 in 100	5 in 100	
90 in 100	10 in 100	
85 in 100	15 in 100	
80 in 100	20 in 100	
75 in 100	25 in 100	
70 in 100	30 in 100	
65 in 100	35 in 100	
60 in 100	40 in 100	
55 in 100	45 in 100	
50 in 100	50 in 100	
45 in 100	55 in 100	
40 in 100	60 in 100	
35 in 100	65 in 100	
30 in 100	70 in 100	
25 in 100	75 in 100	
20 in 100	80 in 100	
15 in 100	85 in 100	
10 in 100	90 in 100	
5 in 100	95 in 100	
0 in 100	100 in 100	
Would prefer Immediate Death		

Please tell the interviewer when you reach this page.

Thank you

COMPREHENSION QUESTIONS.

For the Respondent

Please tick one

How difficult did you find the questions?

Very difficult	○
Quite difficult	○
Neither difficult nor easy	○
Fairly easy	○
Very easy	○

FOR STATES RATED WORSE THAN DEATH.

HEALTH STATE L

CHOICE "A"

You have no problems **walking** about You have no problems with **washing and dressing** You have no problems with your **usual activities** You have no **pain or discomfort** You are not **anxious or depressed**	L You will be confined to **bed** You will be dependent on the nursing staff for help with **using the toilet, dressing and washing** You will be unable to carry out any of your **usual activities** You will be experiencing very severe **pain** in the affected limb that will need morphine to control You will feel extremely **anxious**, **depressed and frightened**

CHOICE "B"

100% CHANCE

IMMEDIATE DEATH

HEALTH STATE L

Please put a tick (✔) against all cases where you are **CONFIDENT** that you would **CHOOSE** the risky treatment in Choice A and a X against all cases where you are **CONFIDENT** that you would **REJECT** the treatment and accept the health state in Choice B.

Please put a = against the case where you think it would be most difficult to choose between having the treatment (Choice B).

THE CHANCES IN CHOICE A:

FOR OFFICE USE ONLY

Chance of Success	**Chance of Failure**	**(✔, X or =)**
100 in 100	0 in 100	
95 in 100	5 in 100	
90 in 100	10 in 100	
85 in 100	15 in 100	
80 in 100	20 in 100	
75 in 100	25 in 100	
70 in 100	30 in 100	
65 in 100	35 in 100	
60 in 100	40 in 100	
55 in 100	45 in 100	
50 in 100	50 in 100	
45 in 100	55 in 100	
40 in 100	60 in 100	
35 in 100	65 in 100	
30 in 100	70 in 100	
25 in 100	75 in 100	
20 in 100	80 in 100	
15 in 100	85 in 100	
10 in 100	90 in 100	
5 in 100	95 in 100	
0 in 100	100 in 100	
Would prefer Immediate Death		

HEALTH STATE M

CHOICE "A"

	M
You have no problems **walking** about You have no problems with **washing and dressing** You have no problems with your **usual activities** You have no **pain or discomfort** You are not **anxious or depressed**	You will be able to **walk** a distance of up to a quarter of a mile with the use of an artificial leg You will need occasional assistance with **washing and dressing** You will have some problems with performing your **usual activities** You will experience "**phantom pain**" in the amputated leg which will cause you some discomfort You will feel **anxious and depressed** for some of the time

CHOICE "B"

100% CHANCE

IMMEDIATE DEATH

<u>HEALTH STATE M</u>

Please put a tick (✔) against all cases where you are **CONFIDENT** that you would **CHOOSE** the risky treatment in Choice A and a X against all cases where you are **CONFIDENT** that you would **REJECT** the treatment and accept the health state in Choice B.

Please put a = against the case where you think it would be most difficult to choose between having the treatment (Choice B).

THE CHANCES IN CHOICE A:

FOR OFFICE USE ONLY

Chance of Success	Chance of Failure	(✔, X or =)
100 in 100	0 in 100	
95 in 100	5 in 100	
90 in 100	10 in 100	
85 in 100	15 in 100	
80 in 100	20 in 100	
75 in 100	25 in 100	
70 in 100	30 in 100	
65 in 100	35 in 100	
60 in 100	40 in 100	
55 in 100	45 in 100	
50 in 100	50 in 100	
45 in 100	55 in 100	
40 in 100	60 in 100	
35 in 100	65 in 100	
30 in 100	70 in 100	
25 in 100	75 in 100	
20 in 100	80 in 100	
15 in 100	85 in 100	
10 in 100	90 in 100	
5 in 100	95 in 100	
0 in 100	100 in 100	
Would prefer Immediate Death		

HEALTH STATE N

CHOICE "A"

You have no problems **walking** about You have no problems with **washing and dressing** You have no problems with your **usual activities** You have no **pain or discomfort** You are not **anxious or depressed**	N You will be confined to a wheelchair You will need assistance with **dressing and washing** You will have a lot of problems performing your **usual activities** You will experience "**phantom pain**" in the amputated leg which will cause you some discomfort You will feel **depressed and anxious**, most of the time.

CHOICE "B"

100% CHANCE

IMMEDIATE DEATH

HEALTH STATE N

Please put a tick (✔) against all cases where you are **CONFIDENT** that you would **CHOOSE** the risky treatment in Choice A and a X against all cases where you are **CONFIDENT** that you would **REJECT** the treatment and accept the health state in Choice B.

Please put a = against the case where you think it would be most difficult to choose between having the treatment (Choice B).

THE CHANCES IN CHOICE A:

FOR OFFICE USE ONLY

Chance of Success	**Chance of Failure**	**(✔, X or =)**
100 in 100	0 in 100	
95 in 100	5 in 100	
90 in 100	10 in 100	
85 in 100	15 in 100	
80 in 100	20 in 100	
75 in 100	25 in 100	
70 in 100	30 in 100	
65 in 100	35 in 100	
60 in 100	40 in 100	
55 in 100	45 in 100	
50 in 100	50 in 100	
45 in 100	55 in 100	
40 in 100	60 in 100	
35 in 100	65 in 100	
30 in 100	70 in 100	
25 in 100	75 in 100	
20 in 100	80 in 100	
15 in 100	85 in 100	
10 in 100	90 in 100	
5 in 100	95 in 100	
0 in 100	100 in 100	
Would prefer Immediate Death		

Appendix 5

Conjoint analysis questionnaire

The following questions are concerned with the importance you place on various aspects of the organisation of vascular services.

For the purposes of the questionnaire we would like you to **imagine** that you need to undergo a **major** vascular operation.

In the questionnaire you will be presented with **8 choices**. In each choice you will be given 2 different descriptions of a vascular service and asked to indicate which one you prefer.

The descriptions of the vascular service differ with respect to the following aspects:

Waiting time – the number of months you must wait between having your vascular problem diagnosed and having an operation. You may have to wait ***3 months***, ***6 months*** or ***9 months***.

Hospital – whether you are treated at your ***local hospital*** or you have to travel to a ***different hospital***.

Mortality – the chance that you will not survive the operation. The chance of not surviving may be ***3 in 100***, ***5 in 100*** or ***7 in 100***.

Amputation – the chance that you need to have a limb amputated. The chance of needing amputation may be ***5 in 100*** or ***8 in 100***.

Length of stay – the average number of days you expect to stay in hospital following your operation. You may have to stay ***12 days*** or ***15 days***.

Staff continuity – whether you see the ***same staff*** or ***different staff*** each time you attend the hospital.

Follow up – whether follow up services are provided ***locally*** or you have to travel to a ***different location***.

Please assume that all other aspects of the vascular services described are the same for each description

For **each** of the **8** choices below, please indicate which description of a vascular service you prefer by putting a tick (✔) in the appropriate box. If you prefer both descriptions equally, please tick both boxes.

Choice 1

	Vascular service A	Vascular service B
Waiting time	9 months	9 months
Hospital	Not local	Not local
Mortality	3 in 100	5 in 100
Amputation	8 in 100	5 in 100
Length of stay	15 days	12 days
Staff continuity	Same staff	Different staff
Follow up services	Provided locally	Provided locally

Please indicate which vascular service you prefer by ticking box A or box B below. If you prefer both equally, tick both boxes.

Vascular service A ☐ Vascular service B ☐

Choice 2

	Vascular service A	Vascular service B
Waiting time	9 months	6 months
Hospital	Local	Not local
Mortality	3 in 100	7 in 100
Amputation	8 in 100	5 in 100
Length of stay	15 days	15 days
Staff continuity	Different staff	Different staff
Follow up services	Not provided locally	Not provided locally

Please indicate which vascular service you prefer by ticking box A or box B below. If you prefer both equally, tick both boxes.

Vascular service A ☐ Vascular service B ☐

Choice 3

	Vascular service A	Vascular service B
Waiting time	9 months	6 months
Hospital	Local	Local
Mortality	3 in 100	3 in 100
Amputation	5 in 100	8 in 100
Length of stay	12 days	12 days
Staff continuity	Different staff	Different staff
Follow up services	Provided locally	Provided locally

Please indicate which vascular service you prefer by ticking box A or box B below. If you prefer both equally, tick both boxes.

Vascular service A ☐ Vascular service B ☐

Choice 4

	Vascular service A	Vascular service B
Waiting time	9 months	6 months
Hospital	Local	Local
Mortality	7 in 100	5 in 100
Amputation	8 in 100	5 in 100
Length of stay	15 days	15 days
Staff continuity	Same staff	Same staff
Follow up services	Provided locally	Provided locally

Please indicate which vascular service you prefer by ticking box A or box B below. If you prefer both equally, tick both boxes.

Vascular service A ☐ Vascular service B ☐

Choice 5

	Vascular service A	Vascular service B
Waiting time	3 months	9 months
Hospital	Local	Not local
Mortality	5 in 100	3 in 100
Amputation	8 in 100	5 in 100
Length of stay	12 days	12 days
Staff continuity	Same staff	Same staff
Follow up services	Not provided locally	Not provided locally

Please indicate which vascular service you prefer by ticking box A or box B below. If you prefer both equally, tick both boxes.

Vascular service A ☐ Vascular service B ☐

Choice 6

	Vascular service A	Vascular service B
Waiting time	3 months	3 months
Hospital	Not local	Not local
Mortality	3 in 100	3 in 100
Amputation	5 in 100	5 in 100
Length of stay	15 days	15 days
Staff continuity	Same staff	Different staff
Follow up services	Provided locally	Not provided locally

Please indicate which vascular service you prefer by ticking box A or box B below. If you prefer both equally, tick both boxes.

Vascular service A ☐ Vascular service B ☐

Choice 7

	Vascular service A	Vascular service B
Waiting time	3 months	9 months
Hospital	Not local	Not local
Mortality	7 in 100	5 in 100
Amputation	8 in 100	8 in 100
Length of stay	12 days	15 days
Staff continuity	Different staff	Different staff
Follow up services	Provided locally	Not provided locally

Please indicate which vascular service you prefer by ticking box A or box B below. If you prefer both equally, tick both boxes.

Vascular service A ☐ Vascular service B ☐

Choice 8

	Vascular service A	Vascular service B
Waiting time	6 months	9 months
Hospital	Not local	Local
Mortality	3 in 100	7 in 100
Amputation	8 in 100	5 in 100
Length of stay	12 days	12 days
Staff continuity	Same staff	Same staff
Follow up services	Not provided locally	Not provided locally

Please indicate which vascular service you prefer by ticking box A or box B below. If you prefer both equally, tick both boxes.

Vascular service A ☐ Vascular service B ☐

Finally, we would be grateful if you would answer some general questions.

1. What vascular condition have you been diagnosed with?

....

2. How do you normally travel to your outpatient appointment?
(please tick)

Ambulance ☐
Hospital car ☐
Private car ☐
Bus ☐
Taxi ☐
Other ☐

If other, please specify below:

....

3. Did you find it difficult to complete this questionnaire?
(please tick)

Yes ☐ Please indicate below what you found difficult

No ☐

....

If you have any comments on this questionnaire, please make them below.

Thank you very much for completing this questionnaire

Please return the completed questionnaire in the enclosed pre-paid envelope

Appendix 6

Guidance for the reconfiguration of vascular services

This appendix provides some evidence-based guidance relating to the configuration of vascular services. The evidence is divided into a number of broad clinical categories that present common problems in management. For each clinical category the evidence is presented in the format of brief bullet points with reference to the relevant publication or section of this report which contains the original research or discussion of the literature. This is followed by consideration of the implications of this evidence for the organisation of services.

Following this are some suggestions regarding possible parameters that may be used as performance indicators for the purpose of audit and clinical governance. These include an indication of possible limits for these parameters and some discussion of the factors that may influence them.

Elective aortic surgery

Evidence

- Patients with small abdominal aortic aneurysms (4 to 5.5 cm) should be observed in a regular ultra-sound surveillance programme and should be considered for surgery if the aortic size exceeds 5.5 cm.[19]
- The test/retest reliability of abdominal ultrasound measurement of aortic size is important and a high degree of repeatability requires regular quality control.[19,252]
- Patients with large aneurysms benefit from surgical repair, including elderly patients (over 80 years old) who are otherwise fit.[253]
- Overall mortality for aortic surgery is considerably higher than published results for specialist centres. (Chapter 4, *The relationship between volume and outcome* (*Local data* and *Published data*))
- There is convincing evidence that surgeons who carry out larger numbers (greater than 12 per year) of major aortic operations have better clinical results. (Chapter 4, *The relationship between volume and outcome* (*Published data*))
- There is some evidence that centres with a regular throughput of aortic surgery have better clinical outcomes. (Chapter 4, *The relationship between volume and outcome* (*Published data*))
- A significant number of patients will require emergency re-operation following elective aortic surgery for complications such as bleeding and limb ischaemia. (Chapter 3, *Secondary procedures*)
- The endovascular treatment of aortic aneurysm is becoming more common, but as yet has no proven role, though the results of large multicentre trials should be available within the next few years.[254]
- There is doubt about the cost benefit of screening for abdominal aortic aneurysms, though there are high-risk subgroups in which it may be appropriate.[255–258]

Implications

- Aortic aneurysms of less than 5.5 cm in diameter should be entered into a surveillance programme with a strict protocol for re-scanning and criteria for surgical intervention.
- There should be an ultrasound surveillance programme, which should have regular quality control regarding the accuracy of measurement.
- Aneurysms that are of sufficient size to require surgery or are expanding rapidly, should be investigated and treated within a period of 1 month from the time of decision to consider intervention.
- A vascular specialist should see all patients with a diagnosis of aortic aneurysm.
- Aortic aneurysm repair should be carried out by surgeons and anaesthetists who have a regular practice of vascular surgery and sufficient experience of major aortic surgery (greater than 12 cases per year).
- Treatment should be carried out in a centre with sufficient expertise and multidisciplinary backup, including HDU/ITU facilities and a specialist emergency vascular surgical cover in case of postoperative complications.
- Endovascular aneurysm repair should only be carried out in centres involved in adequately regulated clinical trials.
- Screening should be available for patients at high risk of aortic aneurysm (e.g. strong family history and PVD).

Suggested audit parameters and considerations

30-day mortality rates for elective aortic surgery

- Major centres with large tertiary referral practice may have a significant number of referrals of complex cases (e.g. juxta-renal aneurysm, inflammatory aneurysm, re-operative cases). This should be considered when interpreting results by separately considering the outcome for local cases and tertiary referrals.
- Overall national rate for 30-day mortality for HRG Q02 is 10.92%, which is considerably higher than most published series. It is likely that these data are distorted by miscoding between elective and emergency cases as the statistics suggest that over 16% of this 'elective' casemix group are emergency admissions. It is, therefore, important to recognise the high rate of incorrect procedural and diagnostic coding between emergency and elective aortic surgery and ruptured and non-ruptured aneurysm. It is probably advisable to define the population as all patients who undergo any abdominal aortic procedure where the mode of admission is elective and to separately consider supra-renal and visceral arterial reconstruction.
- When classified in this way centres expected 30-day mortality rates for elective aortic surgery of greater than 7.5% warrant further investigation.

Waiting time for elective aortic surgery

- Waiting time for elective aortic surgery should be less than 1 month. Extended waiting times for surgery will lead to unnecessary deaths due to patients rupturing aneurysms while awaiting elective surgery.

Rate of elective aortic surgery

- The expected rate for aortic aneurysm repair is approximately 10 per 100,000 population per year. Average figures suggest that approximately 5–10% of cases are over the age of 80 years.

Ultrasound measurement test–retest reliability

- Ultrasound measurement of AAA diameter should be accurate to within 3 mm on retesting.

Leaking or ruptured AAA

- Specialist vascular surgeons obtain better outcomes from surgery on ruptured aneurysm than do non-vascular surgeons. (Chapter 4, *The relationship between volume and outcome* (*Local data* and *Published data*))
- Specialist centres obtain better outcomes than non-specialist centres, despite operating on a higher proportion of those patients admitted with ruptured aneurysm. (Chapter 4, *The relationship between volume and outcome* (*Local data* and *Published data*))
- Patients over the age of 80 years, who survive aortic aneurysm repair, have a similar life expectancy and QoL to an age-matched cohort of the general population.[259]
- Patients who survive aortic aneurysm repair have a high incidence of complications requiring surgical re-intervention, intensive care support and renal support. (Chapter 4, *The relationship between volume and outcome* (*Local data* and *Published data*))
- The majority of patients who require renal support in the postoperative period will have recovery of renal function.[260]

Implications

- A surgeon and team with experience in elective and emergency aortic surgery should manage all patients with suspected abdominal aortic aneurysms.
- Patients should not be excluded from surgical treatment purely on the basis of age.
- Centres treating patients having ruptured or leaking aortic aneurysm should have adequate facilities for postoperative care, including ITU support and preferably renal support.

Suggested audit parameters and considerations

30-day mortality rates for emergency aortic surgery

- Mortality rates are difficult to interpret due to selection that takes place prior to surgery. It is important, therefore to interpret rates in the light of the overall proportion of patients offered surgery.
- As with elective cases, it is important to recognise the high rate of incorrect procedural and diagnostic coding between emergency and elective aortic surgery and ruptured and non-ruptured aneurysm. For this reason it is probably advisable to define the population as all patients with a diagnosis of ruptured and non-ruptured aortic aneurysm or who undergo any abdominal aortic procedure where the mode of admission to hospital is as an emergency.

Rate of admission and surgery for emergency aortic aneurysm

- It is to be expected that over 75% of those patients admitted with ruptured aneurysm will undergo surgery with a 30-day mortality rate of no greater than 45% in those admitted with systolic blood pressure of greater than 70 mmHg.

- It is to be expected that at least 30% of patients over the age of 80 years admitted with ruptured aneurysm will undergo surgery.

Carotid disease

Evidence

- There is strong evidence of a benefit of CE in symptomatic patients with greater than 70% stenosis of the internal carotid artery on the appropriate side. (Chapter 4, *Carotid endarterectomy* (*Published data*))
- The benefit is greatest if the operation is carried out shortly after the development of symptoms and is lost if surgery is delayed for more than 6 months after the most recent event. (Chapter 4, *Carotid endarterectomy* (*Published data*))
- There is considerable variation in reported outcomes for CE and the benefit of surgery depends upon low rates of surgical complications. (Chapter 4, *Carotid endarterectomy* (*Published data*))
- There is evidence for improved results from those surgeons carrying out larger numbers of CEs. (Chapter 4, *The relationship between volume and outcome* (*Published data*))
- Surgery is contraindicated for patients, in whom the stenosis is less than 30% of the lumen diameter. The optimal treatment is in doubt for symptomatic patients with 30–70% stenosis. (Chapter 4, *Carotid endarterectomy* (*Published data*))
- There is doubt about the benefit of treatment for patients with asymptomatic carotid disease. (Chapter 4, *Carotid endarterectomy* (*Published data*))
- Carotid angioplasty and stenting has not been shown to be of proven benefit but is currently being investigated in on-going clinical trials. (Chapter 4, *Carotid endarterectomy* (*Published data*))
- There has been shown to be considerable variability in the rate of CE, between neighbouring districts. (Chapter 4, *Carotid endarterectomy* (*Local data* and *Published data*))

Implications

- Patients with a cerebrovascular event, including transient ischaemic attack, amaurosis or non-disabling stroke should have carotid duplex scan carried out as soon as possible.
- Patients with symptomatic high-grade stenosis (greater than 70% on the appropriate side) should be considered for surgical CE.
- CE should be carried out by a surgeon and surgical team with regular experience of the procedure (greater than ten procedures per year).
- Patients with moderate stenosis and continuing symptoms on best medical treatment should be seen by a vascular surgeon and considered for surgery.
- Patients with asymptomatic carotid stenosis should only be considered for surgery as part of a properly regulated clinical trial.
- Carotid angioplasty and stenting should only be undertaken in centres taking part in properly regulated clinical trials.
- Services should be set up in such a way in that all patients have adequate access to investigation and treatment within 3 months of a cerebrovascular event.

Suggested audit parameters and considerations

30-day mortality and major stroke rates following CE

- Centres treating carotid disease should have audited results of surgical outcomes with a combined 30-day major stroke and mortality of less than 8%.
- Cerebrovascular complications should be assessed by an experienced neurologist.
- The audit should include the indications for surgery as these may have an effect on the expected outcomes.

Waiting time from referral to surgery

- The time from referral to investigation and completion of surgical treatment should be less than 3 months.

Rate of elective carotid surgery

- Expected rates for CE are approximately 10 per 100,000 population per year. This is probably a conservative estimate of the population likely to benefit from the procedure, which is much less frequent in the UK than in other countries with similar incidence of cerebrovascular disease.

Critical ischaemia, acute ischaemia and amputation

Evidence

- The centralisation of vascular service for critical limb ischaemia appears to provide improved outcomes. (Chapter 4, *The relationship between volume and outcome* (*Published data*))
- There is considerable variation in the population-based rates for distal vascular

reconstructive surgery. (Chapter 3, *Admission rates* and *Casemix and demographics*))
- There is an inverse relationship between the rate of vascular reconstruction (in particular distal reconstructive surgery) and rates of amputation. (Chapter 4, *The management of acute ischaemia* (*Local data* and *Published data*))
- Distal vascular reconstruction has a significant limb salvage rate. (Chapter 4, *The management of acute ischaemia* (*Published data*))
- A significant number of patients undergoing distal reconstruction require urgent re-intervention for bleeding or occlusion. (Chapter 3, *Secondary procedures*)
- There is some evidence that graft surveillance by duplex ultrasound can help to identify re-stenosis and thus improve long-term graft patency.[261]
- In selected patients good results are obtained with angioplasty and/or stenting for critical ischaemia.[137]
- Thrombolysis appears to be detrimental for patients with duration of ischaemia greater than 14 days. (Chapter 4, *The management of acute ischaemia* (*Published data*))
- Thrombolysis may be beneficial for patients with short duration of ischaemia and with acute ischaemia due to occlusion of a bypass graft. (Chapter 4, *The management of acute ischaemia* (*Published data*))
- Patients have improved rehabilitation following more distal amputation. (Chapter 4, *Rates of reconstruction and amputation* (*Published data*))
- There is considerable variation in the ratio of above-knee to below-knee amputation. (Chapter 4, *Rates of reconstruction and amputation* (*Local data* and *Published data*))

Implications

- The adequate treatment of acute limb ischaemia and critical ischaemia require the availability of a multidisciplinary approach with the selection of suitable patients for endovascular treatment, including thrombolysis, or surgical treatment.
- Centres treating acute ischaemia should have arrangements for the availability of a vascular surgeon, vascular radiologist and sufficient backup, including emergency vascular radiology facilities at all times.
- All centres managing acute and chronic critical ischaemia should have a full range of services available, including the facilities for carrying out distal bypasses, thrombolysis, stenting and angioplasty.
- No patient should undergo a primary amputation for ischaemia, without having been seen and considered by a vascular specialist.
- Centres should audit the rate and level of amputation.
- Patients in centres carrying out distal bypass surgery and amputation should have access to specialist rehabilitation services.
- Centres carrying out bypass surgery should have the availability of a vascular surgeon to deal with postoperative complications.
- Centres carrying out vascular reconstruction should have access to a graft surveillance programme.

Suggested audit parameters and considerations

30-day mortality rates vascular reconstruction and amputation

- Differences in casemix make it difficult to compare the results of surgery. It is important for audit to consider the entire group of patients with critical ischaemia and be able to separately identify patients undergoing reconstruction for claudication.

Rates of reconstruction and major amputation

- It is difficult to draw conclusions from the rate of reconstruction without evidence of the casemix as regards claudication and critical ischaemia. Collection of data regarding the proportion of distal grafts and the proportion of emergency admissions may help to clarify this.
- The expected rate of distal bypass is 2–3 per 100,000 population per year.
- A rate for major amputation of above 12 per 100,000 population per year warrants further investigation.

Ratio of above to below-knee amputation

- It is to be expected that approximately 60% of major lower limb amputations will be at the below-knee level.

Intermittent claudication

Evidence

- Minor claudication is best treated by lifestyle advice and an exercise programme.[262]
- In some subgroups of patients angioplasty and/or stenting may produce good clinical results. (Chapter 5, *Discussion*)
- Supervised exercise achieves better results than simple advice.[263]
- Smoking cessation is more successful with intensive support.[264]
- Treatment of hypercholesterolaemia is beneficial.[265,266]

- Vein bypass has better patency rate than prosthetic bypass. (Chapter 4, *Material for femoro-popliteal bypass* (*Published data*))
- Failed prosthetic bypass may lead to deterioration in the patient's condition.[139]

Implications

- The treatment of claudication requires a multidisciplinary approach, including lifestyle advice, assistance with smoking cessation, and the availability of both endovascular and surgical options.
- Where bypass surgery is carried out the use of vein is preferable to prosthetic grafts.
- Centres treating claudication should have audited results of the complications following treatment. They should be offering a full range of treatments and prosthetic grafts should very rarely be used for claudication alone.

Suggested audit parameters and considerations

Mortality of reconstruction and angioplasty

- It is important to be able to separately identify the results of bypass surgery and angioplasty carried out for intermittent claudication.
- Mortality rates in this group of patients are expected to be less than 3%.

Rates of reconstruction and angioplasty

- It is to be expected that the majority of claudicants undergoing invasive interventions will be treated by endovascular methods rather than surgery.

Ratio of prosthetic to vein bypasses (in claudicants)

- Very few prosthetic bypasses should be carried out for intermittent claudication.

Varicose veins

Evidence

- There is evidence of considerable variation in practice as regards varicose veins, with surgery often being carried out by unsupervised junior staff.[267]
- There is a high level of recurrence following surgical operations.[268]
- Duplex examination is necessary in complicated or recurrent varicose veins.[269,270]

Implications

- A specialist with appropriate expertise should deal with complicated or recurrent varicose veins.
- Patients with complicated disease should have access to duplex scanning facilities.

Suggested audit parameters and considerations

Rate of surgery for recurrent varicose veins

- Recurrence may occur after several years so that long-term analysis and record linkage may be required.

Deep vein thrombosis

Evidence

- The first choice investigation for deep vein thrombosis is duplex scanning.[271]
- Patients with severe ilio-femoral thrombosis and threatened limb loss may benefit from thrombolysis.[272,273]
- Patients with evidence of pulmonary embolism which recurs on anticoagulation or where they have contraindications to anticoagulation, may benefit from the insertion of a caval filter.[274]

Implications

- All patients with severe ilio-femoral thrombosis, where there is threatened limb loss, should be seen and assessed by a vascular specialist with access to thrombolytic treatment.
- All patients with recurrent pulmonary embolism, despite adequate anticoagulation or who have pulmonary embolus with a contraindication to anticoagulants should be considered for a caval filter.
- Facilities should be available for duplex scanning of patients with suspected deep vein thrombosis as a matter of urgency.

Sub-specialist services

Evidence

- There are a number of conditions, which due to their complexity or rarity, require specialist input from an experienced multidisciplinary team. These include renal artery disease, mesenteric vascular disease, thoracic outlet syndrome, thoraco-abdominal aneurysm and arterio-venous malformation. (Chapter 3, *Admission rates* and *Rates of procedures for provider units*)

Implication

- Patients with the above conditions should have access to tertiary referral, to specialist centres with experience in treating the condition.

Linkages

There are a number of services within a general hospital that may require specialist advice or intervention from vascular radiologists or surgeons.

- Diabetic services require support for patients with foot ulceration – ideally through a joint diabetic clinic and support for diabetic inpatients. (Chapter 8, *Linkages*)
- Renal services require support for vascular access. (Chapter 8, *Linkages*)
- General medical services may need vascular specialists for dealing with the complications of deep vein thrombosis or with cerebrovascular disease. (Chapter 8, *Linkages*)
- Trauma and orthopaedics services require support for problems due to vascular injury. (Chapter 8, *Linkages*)
- Cardiac services may require support for the complications of arterial catheterisation. (Chapter 8, *Linkages*)

Implications

- Centres providing the above services should have a formalised arrangement for the provision of elective, semi-urgent and emergency assistance from vascular specialists.
- These linkages should be taken into account when planning the configuration of services.

Health Technology Assessment panel membership

This report was identified as a priority by the Acute Sector Panel.

Acute Sector Panel

* Previous Chair

continued

continued

Diagnostics and Imaging Panel

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University of Leeds

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Health Technology Assessment 2000; Vol. 4: No. 11

Organisation of vascular services

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We look forward to hearing from you.

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ISSN 1366-5278