

SUMMARY

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Lower Limb Amputation: Working Together

A review of the care received by patients who underwent major lower limb amputation due to vascular disease or diabetes



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A report by the National Confidential Enquiry into Patient Outcome and Death (2014)

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Principal recommendations

A 'best practice' clinical care pathway, supporting the aims of the Vascular Society's Quality Improvement Framework for Major Amputation Surgery, and covering all aspects of the management of patients requiring amputation should be developed. This should include protocols for transfer, the development of a dedicated multidisciplinary team (MDT) for care planning of amputees and access to other medical specialists and health professionals both pre- and post operatively to reflect the standards of the Vascular Society of Great Britain and Ireland, the British Association of Chartered Physiotherapists in Amputee Rehabilitation and the British Society of Rehabilitation Medicine. It should promote greater use of dedicated vascular lists for surgery and the use of multidisciplinary records. (*Vascular Society of Great Britain & Ireland (development), Medical Directors (implementation)*)

All patients with diabetes undergoing lower limb amputation should be reviewed both pre- and post operatively by the specialist diabetes team to optimise control of diabetes and management of co-morbidities. The pre-operative review should not delay the operation in patients requiring emergency surgery. (*Consultant Diabetologists*)

When patients are admitted to hospital as an emergency with limb-threatening ischaemia, including acute diabetic foot problems, they should be assessed by a relevant consultant within 12 hours of the decision to admit or a maximum of 14 hours from the time of arrival at the hospital, in line with current guidance. If this is not a consultant vascular surgeon then one should be asked to review the patient within 24 hours of admission. (*Medical Directors*)

For patients undergoing major limb amputation, planning for rehabilitation and subsequent discharge should commence as soon as the requirement for amputation is identified. All patients should have access to a suitably qualified amputation/discharge co-ordinator. (*Medical Directors*)

As recommended in the Quality Improvement Framework for Major Amputation Surgery (VSGBI), amputations should be done on a planned operating list during normal working hours and within 48 hours of the decision to operate. Any case waiting longer than this should be the subject of local case review to identify reasons for delay and improve subsequent organisation of care. (*Medical Directors*)

Introduction

Peripheral arterial disease (PAD), the result of narrowing or blockage of the arteries, affects approximately 20% of adults older than 55 years in Europe and North America, most often in the lower limbs.¹ The Fontaine Classification describes four stages of PAD: stage I asymptomatic disease; stage II intermittent claudication; stage III rest pain/nocturnal pain; stage IV necrosis/gangrene (with or without rest pain).² Both stages III and IV are the result of advanced PAD³, and may result in limb loss or death if limb revascularisation is either not performed or not technically possible.⁴ In the UK, 500-1000 patients per million population have clinically significant PAD of whom 1-2% will eventually require a lower limb amputation (LLA). The incidence of LLA is 8-15 times higher in diabetics^{5,6} with up to 70% dying within 5 years of surgery.⁶

Hospital inpatient data for 2009/10 showed that there were 5,498 Finished Consultant Episodes (FCEs) for LLA⁷⁻⁹ with 530 deaths in England alone. These rates have remained relatively constant over the last decade although the proportion undergoing above knee amputation has decreased.¹⁰ Previous reports¹¹⁻¹⁵ indicate that the mortality for major lower limb amputation is high in all health economies both within 30-days of surgery (12.4-22%) and at 1 year (38-48%), reflecting the age and co-morbidities of these patients. This and the global epidemic of type II diabetes mellitus (increased from 1.4 x10⁶ to 2.9 x10⁶ in the UK since 1996⁶ and likely to reach 5 x10⁶ by 2025) highlight the potential social and economic impact of critical limb ischaemia on the population, the latter including the costs of hospital care, rehabilitation and ongoing community support. These factors will have significant implications for vascular services.

There is a wide variation in the number of amputations carried out in hospitals across the UK¹⁶ with fewer performed in vascular units that adopt an aggressive approach to limb salvage. Similarly, these centres perform a higher proportion of below knee amputations with better prospects of independent mobility (50% versus 25% for above knee amputation¹⁶).

Peri-operative cardiac complications are the leading cause of morbidity and mortality following surgery¹⁷ and it is therefore important to identify patients with co-morbidities that could be optimised prior to surgery¹⁷ and to ensure that appropriate specialist medical support is available post operatively.

In 2010, the Vascular Society of Great Britain & Ireland published a Quality Improvement Framework for Major Amputation Surgery¹⁸ that aimed to reduce the mortality following surgery to <5% by 2015. The format of this study included collection of data that was designed to determine whether some key indicators within the QIF are being met, such as pre-operative assessment by a specialist multidisciplinary team, access to a named discharge co-ordinator, optimal medical management and appropriate rehabilitation facilities.

Similarly, implementation of guidance published by other organisations¹⁹⁻²¹ on the care of this vulnerable population has been assessed. In particular a detailed review of the management of patients with diabetes has been undertaken.

As a result of this review a series of recommendations have been made in relation to the care of patients undergoing LLA.

1 – Method and Data returns

Method

Expert group

A multidisciplinary group of experts comprising clinicians from vascular surgery, vascular anaesthesia, orthopaedic surgery, rehabilitation medicine, diabetology, nursing, prosthetics, infectious diseases and podiatry contributed to the design of the study and reviewed the findings.

Aim

The aim of the study was:

- To explore remediable factors in the process of care of patients undergoing major lower limb amputation.

Objectives

The expert group identified a number of areas of surgical and medical care to be explored in more detail. These included:

Pre-operative care

- Access to multidisciplinary teams (MDT) (vascular, diabetes, radiology, anaesthesia) and a multiprofessional pathway of care
- Pain management
- Clinical assessment, decision making, grades and specialty of the clinicians providing care, discharge planning and record keeping
- Optimisation of co-morbidities, including diabetic control

Peri-operative care

- The scheduling of surgery, including priority and cancellations
- Seniority of clinicians (surgery and anaesthesia)

- Operation undertaken
- Antibiotic prophylaxis, venous thromboembolism (VTE) prophylaxis
- Diabetes control
- Anaesthetic care

Post operative care

- Access to critical care
- Diabetes control
- Pain management
- Wound care
- Rehabilitation

Organisational factors

- Hub and spoke arrangements
- Management of diabetic foot sepsis including multidisciplinary care & specialties involved
- Access to surgery
- Availability of rehabilitation and prosthetic services
- Submission of data to the National Vascular Database (now National Vascular Registry)

Hospital participation

Organisational data were collected from all hospitals where major lower limb amputation was undertaken, and also where rehabilitation was offered post operatively, in England, Wales, Northern Ireland, the Channel Islands and the Isle of Man. Clinical data were collected from all hospitals where major lower limb amputation was undertaken. Data were collected from both the National Health Service (NHS) and the Independent sector where applicable.

Within each hospital, a named contact, referred to as the NCEPOD Local Reporter, acted as a link between NCEPOD and hospital staff, facilitating case identification, dissemination of questionnaires and data collection.

Study population

All patients aged 16 and over who underwent major lower limb amputation for vascular insufficiency or the complications of diabetes between 1st October 2012

and 31st March 2013, were included in the study. The following codes were identified for inclusion in the study. Inclusion was based on having one code from each column.

OPCS codes for operation	ICD10 codes for disease
X09 – Amputation of leg	<i>Diseases of the circulatory system</i>
X09.1 – Hindquarter amputation	I70 – Atherosclerosis
X09.2 – Disarticulation of hip	I70.0 – Atherosclerosis of aorta
X09.3 – Amputation of leg above-knee	I70.2 – Atherosclerosis of arteries of extremities
X09.4 – Amputation of leg through knee	I70.8 – Atherosclerosis of other arteries
X09.5 – Amputation of leg below-knee	I70.9 – Generalised and unspecified atherosclerosis
X09.8 – Other specified	I73 – Other peripheral vascular disease
X09.9 – Unspecified	I73.0 – Raynaud’s syndrome
X12 – Operations on amputation stump	I73.1 – Thromboangiitis obliterans
X12.1 – Re-amputation at higher level	I73.8 – Other specified peripheral vascular diseases
X12.8 – Other specified	I73.9 – Peripheral vascular disease, unspecified
X12.9 – Unspecified	I74 – Arterial embolism and thrombosis
	I74.0 – Embolism and thrombosis of abdominal aorta
	I74.1 – Embolism and thrombosis of other and unspecified parts of aorta
	I74.3 – Embolism and thrombosis of arteries of lower extremities
	I74.4 – Embolism and thrombosis of arteries of extremities, unspecified
	I74.5 – Embolism and thrombosis of iliac artery
	I74.8 – Embolism and thrombosis of other arteries
	I74.9 – Embolism and thrombosis of unspecified artery
	I77 – Other disorders of arteries and arterioles
	I77.1 – Stricture of artery
	I77.2 – Rupture of artery
	I77.3 – Arterial fibromuscular dysplasia
	I77.6 – Arteritis
	I77.8 – Other specified disorders of arteries and arterioles
	I77.9 – Disorder of arteries and arterioles, unspecified
	<i>Endocrine, nutritional and metabolic diseases</i>
	E10 – Type 1 diabetes (Insulin dependent diabetes mellitus)
	E11 – Type 2 diabetes (Non insulin dependent diabetes mellitus)
	E13 – Other specified diabetes mellitus
	E14 – Unspecified diabetes mellitus

Exclusions

Patients who underwent limb amputation as a result of trauma or malignancy were not included in the study.

Case identification and sampling

The NCEPOD Local Reporter in every hospital was asked to complete a spreadsheet listing all patients who met the relevant criteria for the study. Patient identifiers including the hospital and NHS number were collected alongside the details of the operating clinician. Once the spreadsheets were imported into the study database, cases were randomly sampled to identify seven per hospital and a maximum of three per clinician, to whom a questionnaire was sent for each patient.

Questionnaires and case notes

Organisational questionnaire

At the beginning of the study this was sent to all hospitals where lower limb amputation was reported to be undertaken, and also hospitals where rehabilitation was offered post operatively. This questionnaire collected data about staffing and facilities, inpatient care and also post-amputation care.

Clinical questionnaires

A questionnaire was sent to the consultant surgeon who was responsible for the patient's care at the time of the procedure. This collected data around the admission process, pre-operative care and preparation (including consent), the operation undertaken, post operative care and pain management, and the discharge process. Where relevant, data were also collected about diabetes management.

Case notes

The following case notes extracts were requested, for the duration of the patient's admission:

- Medical notes from admission to discharge
- Notes from multidisciplinary team meetings
- Imaging reports
- Consent forms
- Pre-anaesthetic assessment records
- Operation notes
- Anaesthetic charts
- Recovery room records
- Integrated care pathways
- Nursing notes
- Assessment and treatment reports by physiotherapy, occupational therapy and other rehabilitation services
- DNACPR documentation
- Autopsy report (where applicable)
- Drug charts
- Fluid balance charts
- Haematology and biochemistry results including data on peri-operative glucose control
- Critical care charts
- End of life care pathway

Advisor group

A multidisciplinary group of Advisors was recruited to undertake peer review of a sample of the case notes and the associated questionnaire. This group of Advisors comprised clinicians from a number of specialties including vascular surgery and vascular anaesthesia, general anaesthesia, orthopaedic surgery, diabetes, general medicine, rehabilitation medicine, physiotherapy and occupational therapy, nursing (diabetes nurse specialists and vascular nurse specialists) and podiatry.

All patient identifiers were removed from the case notes and questionnaires prior to review. Neither the Clinical Co-ordinators at NCEPOD, nor the Advisors, had access to patient identifiable information.

After being anonymised, each case was reviewed by at least one Advisor within a multidisciplinary group. At regular intervals throughout the meeting, the Chair (an NCEPOD Clinical Co-ordinator) allowed a period of discussion for each Advisor to summarise their cases and ask for opinions from other specialties or raise aspects of care for discussion.

Advisors reviewed each case using a semi-structured assessment form. Data were entered into a database comprising quantitative tick-boxes and qualitative free text. Where the Advisor stated that there was insufficient information available in the case note extracts to make a decision, there was the option to select 'unable to answer'.

The grading system shown in Figure 1.1 was used by the Advisors to grade the overall care that each patient received.

Good practice: a standard of care you would expect from yourself, your trainees, and your institution
Room for improvement: aspects of **clinical** care that could have been better
Room for improvement: aspects of **organisational** care that could have been better
Room for improvement: aspects of **clinical and organisational** care that could have been better
Less than satisfactory: several aspects of **clinical and/or organisational** care that were well below a standard you would expect from yourself, your trainees and institution
Insufficient data: Insufficient information submitted to NCEPOD to assess the quality of care

Figure 1.1 NCEPOD assessment of overall quality of care

Quality and confidentiality

Each case was given a unique NCEPOD number. The data from all questionnaires received were electronically scanned into a preset database. Prior to any analysis taking place, the data were cleaned to ensure that there were no duplicate records, and that erroneous data had not been entered during scanning. Any fields that contained data that could not be validated were removed. Section 251 approval had been gained to collect these data.

Data analysis

Following cleaning of the quantitative data, descriptive data summaries were produced.

The qualitative data collected from the Advisors' opinions and free text answers in the clinician questionnaire were coded, where applicable, according to content to allow quantitative analysis. The data were reviewed by NCEPOD Clinical Co-ordinators, a Clinical Researcher, and a Researcher, to identify the nature and frequency of recurring themes.

All data were analysed using Microsoft Access and Excel by the research staff at NCEPOD.

The findings of the report were reviewed by the Expert Group, Advisors, and the NCEPOD Steering Group prior to publication.

Case studies have been used throughout this report to illustrate particular themes.

Data returns

During the six-month period (1st October 2012 – 31st March 2013) details on 1986 cases were returned to NCEPOD. From this group 103 patients were excluded as they did not meet the study criteria (i.e. the amputation was not undertaken as a result of vascular disease or diabetes), or were identified as duplicate cases. A further 760 cases were randomly sampled to be included in the study (maximum of seven per hospital, and up to three per clinician). In total 642 clinical questionnaires (84%) and 628 (83%) sets of case notes were returned. In terms of complete data sets (case notes and the clinical questionnaire) 596/760 were returned (78%) (Figure 1.2).

A number of questionnaires were returned blank or NCEPOD was notified of problems in terms of questionnaire completion. The most common reason for this was that the consultant who undertook the operation was no longer at the hospital. Further to this, in some cases the case notes that were returned were too incomplete or were returned after the deadline and so could not be included in the Advisor assessment.

Study sample denominator by chapter

Within this study the denominator will change for each chapter and occasionally within each chapter. This is because data have been taken from different sources depending on the analysis required. For example, in some cases the data presented will be a total from a question taken from the clinical questionnaire only, whereas some analysis may have required data from the clinical questionnaire and data from the Advisor assessment form.

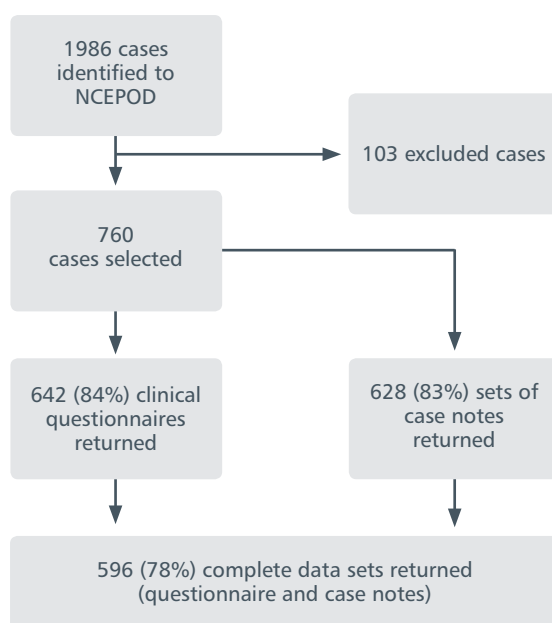


Figure 1.2 Data returns

Key findings

The organisation of care

1. 102/123 (82.9%) hospitals had written protocols and/or pathways of care for the transfer of patients between hospitals involved in a shared vascular rota.
2. 116/136 (85.3%) hospitals stated that their vascular unit submits data to the NVD. Only 68/116 (58.6%) hospitals submitted data to the British Society for Interventional Radiology (BSIR) database.
3. Only 49/135 (36.3%) hospitals had a discharge co-ordinator responsible for amputees.
4. 82/140 (58.6%) hospitals had a multidisciplinary team responsible for the care of patients undergoing lower limb amputation in the hospital.
5. Review by rehabilitation specialists prior to surgery was low; (consultant in rehabilitation medicine = 14/127; occupational therapist = 74/132; podiatrist = 48/127; prosthetics = 24/127). The number of hospitals where rehabilitation physiotherapists reviewed patients prior to surgery was also low, (87/133; 65.4%).
6. 60/134 (44.8%) hospitals had a policy or protocol for the care of patients undergoing major amputation.
7. Consultants in rehabilitation medicine were present in 136/236 (57.6%) hospitals where amputation was undertaken or rehabilitation was offered.
8. Prosthetic services were available on-site in 52/244 (21.3%) hospitals; where they were not available the nearest service was on average 21 miles away.
9. The VSGBI states that there should be a formal process for referrals to a specialist amputee rehabilitation team (prosthetics); this was the case in 124/169 (73.4%) hospitals. 36/169 (21.3%) hospitals had informal arrangements; 9/169 (5.3%) hospitals had no arrangement.
10. Specialist domiciliary physiotherapy services were available to patients from 81/215 (37.7%) hospitals; domiciliary occupational therapy services were available to patients from 90/214 (42.1%) hospitals.
11. Only 111/230 (48.3%) hospitals routinely provided written advice or a care pathway to those responsible for an amputee's management following discharge from hospital.
12. 158/181 (87.3%) District General Hospitals and University Teaching Hospitals reported having an acute pain management team. Where an acute pain team was available, they were reported as routinely seeing amputees prior to surgery in only 50/161 (31.3%) of hospitals.

Admission to hospital

1. Delays in the transfer of patients to vascular units occurred in 21/145 (14.5%) patients and affected 15/105 (14.2%) emergency transfers.
2. 493/605 (81.5%) patients were initially admitted to general, vascular or assessment wards and in 447/554 (81%) cases the admitting doctor was from a surgical speciality.
3. 73/172 (42.4%) emergency admissions were reviewed by a consultant within 14 hours of admission although the time of first consultant review was not documented in 268/529 (50.6%) cases.
4. The initial management plan was either not clear or was inappropriate in 60/498 (12%) cases.
5. 47/109 (43.1%) patients admitted electively were seen in a pre-assessment clinic.
6. Major co-morbidity was often present. 493/628 (78.5%) of patients had at least one of diabetes, cardiovascular disease, renal failure, or respiratory disease. In cases reviewed by Advisors, there was potential to improve co-morbidities pre-operatively in just under a third (147/457; 32.2%).
7. 210/529 (39.7%) patients underwent pre-operative review by a specialist physician (not including anaesthetics), and Advisors thought that review was indicated in a further 120/529 (22.7%) cases. In total, medical review either took place or was indicated in 330/529 (62.4%) cases.
8. Only 280/460 (60.9%) patients had a pre-operative nutrition score calculated.

Peri-operative care

1. For patients admitted under other specialties the Advisors considered that earlier review by a consultant vascular surgeon might have altered the outcome in 16/148 (10.8%) patients in whom they were able to give an opinion.
2. Deficiencies in note keeping are a recurrent theme throughout this study.
3. 244/622 (39.2%) patients had no formal vascular imaging performed, and the Advisors considered that assessment was inadequate in 37/481 (7.7%) cases.
4. In 76/504 (15.1%) patients the Advisors considered that surgery was unnecessarily delayed.
5. The Advisors felt that amputation might have been avoided in 22/286 (7.7%) patients, in whom they were able to make a judgment, had limb salvage been attempted.
6. The proportion of amputees who underwent pre-operative review by a physiotherapist, a diabetes nurse specialist and a vascular nurse specialist were poor. The data were worse when considering assessment by an amputee co-ordinator or a psychologist.
7. In 356/520 (68.5%) patients there was no pre-operative discussion of discharge planning and rehabilitation.
8. 452/516 (87.6%) patients did not have a named individual responsible for co-ordinating discharge planning and rehabilitation.
9. In 72/499 (14.4%) patients the Advisors considered that the quality of the pre-operative care was poor or unacceptable.
10. The Advisors did not think the seniority of the person taking consent was appropriate in 53/452 (11.7%) patients and found that the risks and benefits of surgery were not adequately documented in a third of cases, (144/454; 31.7%). The risk of death following the procedure was only included on the consent form in 105/479 (21.9%) of patients.
11. 88/579 (15.2%) patients did not undergo MRSA screening despite national guidelines.
12. 138/304 (45.4%) patients who were classified as requiring expedited or elective amputation underwent surgery in the emergency theatre. Further, it is likely that a proportion of those said to require urgent surgery should have had their operation on a planned list.
13. When surgery was delayed this was thought to affect outcome in (14/64) patients. Two-thirds of all delays would have been avoided if surgery had been performed on a planned operating list.
14. The level of anaesthetic support for patients undergoing amputation was generally good. However, deficiencies in record keeping were noted in respect of pre-operative assessment, administration of peri-operative antibiotics, and recording the grade of anaesthetist.

The operation

1. Unsupervised non-consultant grades and trainees performed just under a third of amputations (175/603; 29%). In 122/603 (20.2%) the most senior surgeon present in the operating theatre was a non CCT specialist registrar (ST3 and above) or a core surgical trainee.
2. The Advisors considered that amputation was inappropriate in 35/479 (7.3%) of cases. In 15 of these patients either revascularisation or conservative management were considered more appropriate, highlighting the need for a dedicated MDT.

Post operative care

1. Following amputation, stump-related complications were common; cellulitis 66/437 (15.1%); breakdown 89/437 (20.4%); and contracture 9/405 (2.2%); and were higher, particularly for stump breakdown when trainees performed the surgery. (38/262; 14.5% vs. 47/239; 19.7% consultant/trainee with CCT vs. trainee grade).
2. Stump breakdown occurred twice as often in patients undergoing below-knee amputation (44/166 (26.5%) vs. 27/201 (13.4%) above-knee amputation). The frequency of stump complications in this study was higher than in a contemporary study from the USA.
3. 249/529 (47.1%) patients experienced other complications of which chest infection was the most common (102/628; 16.2%). The frequency of medical complications suggests that regular, routine medical review of amputees would be beneficial.
4. 313/529 (59.2%) patients required post operative review by a physician.
5. The 30-day mortality for major limb amputation in this study was 12.4% (77/622).

Pain management

1. Pre-operative pain control was only considered as 'good' by the Advisors in 100/438 (22.8%) patients. Review by the acute pain team would have been appropriate in 93/185 (50.3%) patients who were not seen pre-operatively.
2. Post operative pain control was better but was only assessed as 'good' in 174/464 (37.5%) patients.

Falls, rehabilitation and discharge

1. Falls occurred in 66/515 (12.8%) of the cases assessed by Advisors. In 112/384 (29.2%) cases, Advisors found no evidence of a falls assessment.
2. In 91/409 (22.2%) cases assessed by Advisors, additional non-medical professional review would have been appropriate. Most commonly this related to psychologists (38/75) or specialist amputee rehabilitation services (33/45).
3. In 103/160 (64.4%) cases assessed by the therapy Advisors, there was no evidence that physiotherapy commenced pre-operatively. In 68/151 (45%), physiotherapy did not commence on the first post operative day.
4. Documentation of therapy input was much easier to assess when multidisciplinary records were used.
5. In 60/143 (42%) cases there was no evidence in the case notes of a decision being made regarding the suitability of the patient for limb prosthesis prior to discharge.
6. There were 75/143 (52.4%) cases of delayed discharge for non-medical reasons identified by the Advisors.

Diabetes care

1. 349/628 (55.6%) patients included in the study had diabetes. Patients with diabetes had a higher than average incidence of both type 1 diabetes and insulin use compared to the general population.
2. Only 41/310 (12.8%) patients with diabetes were admitted under the care of the diabetes service.
3. 160/274 (58.4%) patients with diabetes were reviewed pre-operatively by a diabetes nurse specialist.
4. The Advisors considered that glycaemic control was poor or unacceptable in 43/161 (26.7%) patients at some point within the surgical pathway.
5. Prescribing errors for both insulin and oral hypoglycaemic agents occurred commonly. The failure to prescribe insulin dose (unit abbreviated to 'U' or written unclearly) was the most frequent error occurring in 45/279 (16.1%) patients.

Organisational data

7. 140/143 (97.9%) hospitals had clinical/diabetes nurse specialists, however, where present they routinely reviewed patients under the care of the vascular unit in only 73/132 (55.3%) hospitals.
8. Diabetic foot clinics were present in 130/143 (90.9%) of hospitals.
9. Although diabetes specialists are the main specialty involved in the staffing of diabetes foot clinics (always present in 106/125 hospitals), diabetology input was less frequent at the point of MDT discussion (51/107 hospitals) and there was no presence at morbidity and mortality meetings.

Outcomes

1. Many of the aims of the Vascular Society of Great Britain & Ireland's Quality Improvement Framework have not been implemented by the clinicians submitting data to this study.

Recommendations

- 1) A 'best practice' clinical care pathway, supporting the aims of the Vascular Society's Quality Improvement Framework for Major Amputation Surgery, and covering all aspects of the management of patients requiring amputation should be developed. This should include protocols for transfer, the development of a dedicated multidisciplinary team (MDT) for care planning of amputees and access to other medical specialists and health professionals both pre- and post operatively to reflect the standards of the Vascular Society of Great Britain and Ireland, the British Association of Chartered Physiotherapists in Amputee Rehabilitation and the British Society of Rehabilitation Medicine. It should promote greater use of dedicated vascular lists for surgery and the use of multidisciplinary records. (*Vascular Society of Great Britain & Ireland (development), Medical Directors (implementation)*)
- 2) All patients with diabetes undergoing lower limb amputation should be reviewed both pre- and post operatively by the specialist diabetes team to optimise control of diabetes and management of co-morbidities. The pre-operative review should not delay the operation in patients requiring emergency surgery. (*Consultant Diabetologists*)
- 3) As recommended in the Quality Improvement Framework for Major Amputation Surgery (VSGBI), all patients undergoing major lower limb amputation should have a named individual responsible for the co-ordination of their rehabilitation and discharge (amputation/discharge co-ordinator). Their role should include the provision of detailed written information for patients and their relatives covering the whole clinical pathway. (*Medical Directors, Clinical Directors*)
- 4) The decision to undertake a major amputation should be made by a multidisciplinary team (MDT) including vascular surgery, physiotherapy, occupational therapy, diabetology, radiology, specialist nursing and an amputation/discharge co-ordinator. Where the urgency of surgery prevents this, as a minimum patients should be discussed with a consultant vascular surgeon and reviewed by a consultant anaesthetist, before amputation. (*Medical Directors*)
- 5) All Trusts should have formal access to a consultant service in rehabilitation medicine that includes the post operative care of patients after major lower limb amputation. (*Medical Directors*)
- 6) When patients are admitted to hospital as an emergency with limb-threatening ischaemia, including acute diabetic foot problems, they should be assessed by a relevant consultant within 12 hours of the decision to admit or a maximum of 14 hours from the time of arrival at the hospital, in line with current guidance. If this is not a consultant vascular surgeon then one should be asked to review the patient within 24 hours of admission. (*Medical Directors*)
- 7) A model for the medical care of amputees, should be introduced which includes regular review by a physician and a surgeon throughout the in-patient stay. The existing orthogeriatric model serves as a good example in current practice. (*Medical Directors and Specialist Commissioners*)
- 8) NICE recommends that a nutritional assessment of all patients should be made within the first 48 hours of admission (CG32). This guidance should be implemented for all patients requiring lower limb amputation. (*All Health Care Professionals*)

- 9) All patients admitted electively for lower limb amputation should be seen in a pre-assessment clinic to optimise medical co-morbidities and to plan post operative rehabilitation. *(Clinical Directors, Consultant Anaesthetists)*
- 10) For patients undergoing major limb amputation, planning for rehabilitation and subsequent discharge should commence as soon as the requirement for amputation is identified. All patients should have access to a suitably qualified amputation/discharge co-ordinator. *(Medical Directors)*
- 11) Clear guidelines on obtaining consent from patients requiring amputation should be developed to address the deficiencies identified in this study. *(Vascular Society of Great Britain & Ireland)*
- 12) A consultant vascular surgeon should be present in the operating theatre for all amputations performed by a non-CCT trainee. *(Medical Directors)*
- 13) A care bundle should be developed to ensure the structured management of amputation patients. Audit of this should form part of the National Vascular Registry *(Vascular Society of Great Britain & Ireland, Vascular Anaesthesia Society of Great Britain and Ireland)*
- 14) All patients undergoing lower limb amputation must be screened pre-operatively for MRSA, as recommended by the Department of Health. *(All Consultant Surgeons)*
- 15) As recommended in the Quality Improvement Framework for Major Amputation Surgery (VSGBI), amputations should be done on a planned operating list during normal working hours and within 48 hours of the decision to operate. Any case waiting longer than this should be the subject of local case review to identify reasons for delay and improve subsequent organisation of care. *(Medical Directors)*
- 16) Hospitals require a properly funded and staffed acute pain service with capacity to manage patients with critical limb ischaemia and both pre- and post-amputation pain. *(Medical Directors)*
- 17) Insulin should be prescribed according to National Patient Safety Agency (NPSA) recommendations. *(All Doctors)*
- 18) Hospitals should have clear guidelines for the management of blood glucose levels when they are outside the acceptable range. These guidelines should be implemented for all patients undergoing lower limb amputation. *(Medical Directors, All Consultants)*
- 19) A falls risk assessment should be undertaken in all patients undergoing lower limb amputation, and measures should be put in place to reduce the risk of a subsequent fall during the in-patient stay. *(Medical Directors, Physiotherapists)*
- 20) As recommended by the British Association of Chartered Physiotherapists in Amputee Rehabilitation and British Society of Rehabilitation Medicine, when it is possible to choose the level of amputation, the physiotherapist should be consulted in the decision making process regarding the most functional level of amputation for the individual. Post operative physiotherapy should commence on the first day where possible and should include exercise, oedema management and use of early walking aids as appropriate. *(Consultant Vascular Surgeons, Physiotherapists)*

11 – Overall quality of care

Overall quality of care

The Advisors were asked to grade the level of care of each case considering all aspects of management. Their opinion is presented in Figure 11.1.

This assessment is disappointing with only 229/519 (44.1%) of patients receiving a standard of care with which the Advisors would be happy for themselves or

their family and friends. Of the remainder there was room for improvement in clinical care in all but 10%. In other words clinical management could have been better in half of the patients included in the study.

This highlights the urgent need for implementation of the Quality Improvement Framework proposed by the Vascular Society of Great Britain and Ireland and the recommendations made in this report.

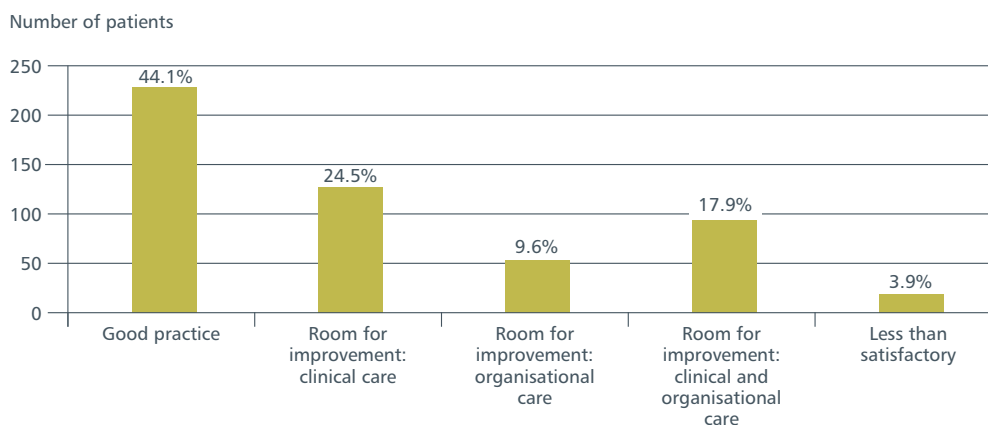


Figure 11.1 Overall assessment of care (Advisors' opinion)

Summary

Although amputation is often perceived as a simple procedure, this study has demonstrated that the pathway of care is complex. This complexity brings with it the challenge of organising appropriate acute medical and surgical care and providing subsequent rehabilitation. Better co-ordination of these aspects of management is required to deliver good care.

In the care pathway, there were often delays. These included delay in referral to and in review by a vascular surgeon and then between the decision to operate and the operation itself. The consent form was frequently found to be inadequate, failing to detail the benefits of the procedure as well as serious complications including mortality. The operation was often performed out of hours in an emergency operating theatre and unsupervised non-consultant grade surgeons did a third of all amputations. Post operatively both medical and surgical complications occurred frequently. There is clear room to improve practice in these areas.

Co-existing medical problems were common and occurred in both the pre- and post operative periods. These frequently required non-surgical specialist care but this was provided inconsistently. More than half of the patients had diabetes and blood sugar control was often poorly managed. There were other care issues related to diabetes which could be improved by routine involvement of the specialist diabetes team.

Pain was also a common feature throughout the peri-operative period. Optimal pain management was not consistently provided. Pain also limited the ability of the therapy teams to commence rehabilitation. Review of all patients by a specialist pain team would improve patient experience and has the potential to improve early mobilisation and shorten length of stay.

Physiotherapists were often not involved early enough in the patient pathway. Structured involvement of physiotherapists in the multidisciplinary team should include pre-operative discussion of rehabilitation potential and the level of amputation as well as early post operative rehabilitation and co-ordination of discharge plans.

In addition to improved co-ordination of specialist involvement for these patients, other apparently small details have the potential to improve patient experience and outcomes. Screening for MRSA, nutritional assessment, falls risk assessment and documentation of timely antibiotic administration all fell below an acceptable level.

The development of a co-ordinated pathway, which delivers care by all of the relevant specialists when it is needed, should ensure delivery of optimum care and improve outcomes. The National Vascular Database provides an opportunity to measure the standards set within this pathway and would enable units to assess their own performance and potentially reduce mortality to <5%, the target set by the Vascular Society of Great Britain and Ireland.

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