What is a scoping report?
Scoping reports ascertain the quantity and quality of the published clinical and cost effectiveness evidence on health technologies under consideration by decision makers within NHSScotland. They also serve to clarify definitions related to the research question(s) on that topic. They are intended to provide an overview of the evidence base, including gaps and uncertainties, and inform decisions on the feasibility of producing an evidence review product on the topic. Scoping reports are undertaken in an approximately 1 month period. They are based upon a high level literature search and selection of the best evidence that Healthcare Improvement Scotland could identify within the time available. The reports are subject to peer review but do not undergo external consultation. Scoping reports do not make recommendations for NHSScotland.

Key definitions

Vascular services: deal with disorders of the arteries, veins and lymphatics, and comprise vascular surgery, interventional radiology and linkages to other specialities and support services that patients undergoing vascular procedures may require.

Background
A review of vascular services in Scotland is currently being undertaken under the auspices of the National Planning Forum. The gradual emergence of vascular surgery and vascular radiology as sub-specialities presents challenges to achieving the optimum delivery of vascular services. Consideration needs to be given to the extent to which the configuration of services affects patient outcomes. One aspect of this is how reconfiguration of vascular services might impact on rates of major limb amputation.

The following question was scoped:
1. What implications does the organisation of vascular services have for rates of amputation?

Literature search
A systematic search of the literature was conducted between 6–11 July 2011. Key resources were searched for reviews, guidelines and economic studies. Search terms included major limb amputation, service reconfiguration, reorganisation, restructuring, centralisation, decentralisation, utilisation.

The following databases were searched:
- Medline (via OVID)
- Embase (via OVID)
- CINAHL (via EBSCOhost)
- Web of Knowledge.

Results were limited to English language. A full list of resources searched and search strategies are available on request.

Evidence base

Table 1 Included evidence sources

<table>
<thead>
<tr>
<th>Publication type</th>
<th>Number of publications</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health technology assessment</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Retrospective longitudinal study</td>
<td>5</td>
<td>2-6</td>
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Only the evidence sources identified by the scoping literature search are included in the table.

Findings

1. What implications does the organisation of vascular services have for rates of amputation?

The literature search identified one United Kingdom (UK) health technology assessment (HTA) published in 2000 that evaluated clinical outcome implications of the organisation of vascular services and undertook modelling to predict cost and outcome effects of reconfiguration. The HTA identified differences in practice and workload in North Trent (1995–1997) that could have implications for outcomes, including amputation, and reviewed published literature (1986–1998) to ascertain how reconfiguration of services might influence those outcomes — this included the volume-outcome relationship for vascular surgical procedures, and the availability of particular procedures. Healthcare Improvement Scotland has provided scoping reports on hospital volume-outcome literature for abdominal aortic aneurysm repair.
and carotid endarterectomy. This scoping report does not include volume-outcome studies.

The HTA reviewed longitudinal and cross-sectional studies of the relationship between the provision of vascular reconstruction and the rate of major amputations published to 1998 (this was not a full systematic review). This suggested an association between higher rates of vascular reconstruction and lower rates of major amputation, and a higher proportion of more distal amputations. One of the included studies was conducted in the UK, a prospective audit in the Oxford region that showed lower amputation rates in districts with a high volume of distal arterial reconstructions compared with low volume districts (high and low volume were defined as above and below the regional average, respectively). The HTA noted that the audit lacked adjustment for volume districts (high and low volume were defined as above and below the regional average, respectively). The HTA reviewed longitudinal and cross-sectional studies of the relationship between the provision of vascular reconstruction and the rate of major amputations published to 1998 (this was not a full systematic review). This suggested an association between higher rates of vascular reconstruction and lower rates of major amputation, and a higher proportion of more distal amputations. One of the included studies was conducted in the UK, a prospective audit in the Oxford region that showed lower amputation rates in districts with a high volume of distal arterial reconstructions compared with low volume districts (high and low volume were defined as above and below the regional average, respectively). The HTA noted that the audit lacked adjustment for case mix. Holdsworth et al. subsequently published a retrospective longitudinal study (1989–1999) of the provision of distal arterial reconstruction in Scotland, which showed lower rates of reconstruction in Scotland compared with other European countries. Marked regional variation in distal reconstruction in Scotland was not, however, reflected in variation in lower limb amputation rates, leading the authors to posit that insufficient distal surgery was being undertaken in Scotland at that time to impact on amputation. The HTA considered three main options in an operational model to predict the effects of service reconfiguration, using data from the North Trent hospitals district (1995–1997):

- devolved (the current situation at that time);
- centralised; and
- hub-and-spoke (major vascular centre (hub) and smaller hospital (spoke)).

Each option had sub-options relating to workload and case mix based on current activity or increased activity to match the central rates for PVD, or PVD and carotid surgery. Major amputation, below-knee amputation, vascular reconstructions and angioplasties were among the parameters identified as possible indicators of outcome. Modelling showed considerable variation in the distribution of workload depending on the model adopted, and suggested that a fully centralised service would have little cost or outcome advantage over a hub-and-spoke arrangement. Running the model considering only changes in the management of PVD to match that in the central hospital showed an expected reduction in the number of major amputations, a greater proportion of below the knee amputations, an increase in the number of vascular reconstructions, a decrease in the use of prosthetic grafts, and an increase in the number of angioplasties. The HTA reviewed published literature on the availability and use of angioplasty (endovascular revascularisation) for peripheral vascular disease (PVD), finding that increases in the use of angioplasty reported in early studies did not appear to be associated with a significant decline in amputations (again, this was not a full systematic review). Four recent studies of national trends in endovascular treatment and outcomes for lower extremity peripheral arterial disease (PAD) in the United States of America (USA) were identified by J Brittenden and the HTA, including vascular surgery, was given to NHS boards in March this year and will go into the public domain in October. Data for patients admitted between July 2009–June 2010 indicate marked variation across NHS boards in standardised lower limb revascularisation rates per 100,000 population, with 7/14 boards lying either above or below the outer control limits of 3 standard deviations from the average. Standardised lower limb (leg) amputation rates show much less variation, with the majority of boards lying within 2 standard deviations of the average, and all boards lying within the outer control limits of 3 standard deviations. National trends suggest little variation in crude rates of lower limb revascularisation procedures per 100,000 population between July 2005–June 2010, and no definite overall increase or decrease in lower limb amputations.

The Vascular Society of Great Britain and Ireland (VSGBI) provision of services report shows NHS statistics illustrating an upward trend in the numbers of endovascular interventions for leg ischaemia and a slight decrease in surgical reconstructions in England from 1999/2000 to 2006/2007. The HTA reviewed published literature on the availability and use of angioplasty (endovascular revascularisation) for peripheral vascular disease (PVD), finding that increases in the use of angioplasty reported in early studies did not appear to be associated with a significant decline in amputations (again, this was not a full systematic review). Four recent studies of national trends in endovascular treatment and outcomes for lower extremity peripheral arterial disease (PAD) in the United States of America (USA) were identified by J Brittenden and the scoping literature search. These were retrospective analyses of Medicare claims or Nationwide Inpatient Sample administrative data (together with New York State inpatient hospitalisation and outpatient surgeries discharge data in one study). The time periods covered were 1996–2005, 1996–2006, 1998–2007, and 2001–2003, and the unit of analysis was the procedure/admission, not the patient. All four studies reported trends towards increasing use of endovascular techniques, fewer open revascularisation procedures, and fewer major lower extremity amputations. The authors concluded that their analyses suggested an association between increased use of endovascular technology and reduced rates of amputation in patients with PAD, but do not establish causality, and listed various other factors that are likely contributors to the observed decline in amputation rates.
vascular teams have lower amputation rates for critical lower limb ischaemia; patients are more likely to undergo amputation in hospitals with low volumes of vascular surgery rather than be transferred to an adjacent high volume hospital to access limb salvage surgery; and patients may suffer unnecessary amputations unless they have access to the full range of vascular services.

**Additional information**

After the scoping literature search had been undertaken, the working group suggested the impact of diabetic multidisciplinary teams (MDTs) on amputation rates as another aspect of service organisation worthy of consideration. Several published studies relating to this topic, and to the provision of angioplasty, identified by the steering group working group are summarised below. As this evidence was not identified by the systematic scoping literature search it may not be comprehensive.

Scottish Intercollegiate Guidelines Network (SIGN) guidelines recommend that patients with active diabetic foot disease should be referred to a multidisciplinary diabetic foot care service (grade of recommendation C). National Institute for Health and Clinical Excellence (NICE) guidelines on diabetic foot problems recommend that each hospital should have a care pathway for patients with diabetic foot problems who require inpatient care and that this should be managed by a multidisciplinary foot care team. The recommendations were based on consensus among the guideline development group in light of very low quality evidence from a systematic review of five cohort studies that compared a pathway or MDT approach with standard care and reported reductions in amputation rates.

The NHS atlas of variation in healthcare illustrated a two-fold variation across strategic health authorities in England in the incidence of major amputations in diabetes-related amputations over time in the UK and the Netherlands. The UK study, a largely prospective audit carried out at Ipswich hospital, reported a 40.3% reduction in the incidence of total diabetic amputations, and a 61.5% reduction in the incidence of major diabetic amputations, per 100,000 of the general population between 1995–2005. The corresponding reductions per 10,000 people with diabetes were 70.0% and 81.6%. In the Netherlands there was a 34% reduction in the incidence of diabetes-related lower extremity amputation per 10,000 people with diabetes between 1991–2000 (p<0.05), based on retrospective analysis of national registry data. The authors of the UK study noted that the improvements in outcome followed improvements in foot care including MDT working, as well as improvements in vascular, radiological and microbiological services, but did not provide supporting data. The authors of the Netherlands study suggested that the reduction in amputations might reflect increased attention to the diabetic foot, referring to other sources that reported increasing numbers of multidisciplinary foot clinics and hospital podiatrists. An earlier Danish single-centre retrospective case series (1981–1995), identified through the steering group working group, reported a decrease in major amputations in people with diabetes coinciding with an increase in revascularisation procedures and the establishment of a multidisciplinary diabetic foot clinic.

With respect to the provision of angioplasty, the working group highlighted the findings from the UK Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) multicentre randomised controlled trial (RCT) that found no statistically significant difference in amputation-free or overall survival and no difference in health related quality of life between surgical bypass-first and angioplasty-first treatment strategies. The trial recommended that patients expected to live ≥2 years should probably be offered surgical bypass first, and patients expected to live <2 years are probably better served by angioplasty first. SIGN guidelines on diabetes management cited the BASIL trial and observational studies in support of a recommendation that patients with critical limb ischaemia should be considered for arterial reconstruction (bypass/angioplasty). Two recently published case series from the Netherlands and Italy were identified by I Robertson. The Netherlands single-centre retrospective case series (2006–2008) reported on patients with critical limb ischemia who had no surgical options for revascularisation and were scheduled for amputation and who underwent angioplasty (64% had diabetes); it reported that no amputation was needed in 10/26 limbs (n=25 patients). The Italian single-centre case series (2002–2007) reported on diabetic patients with critical limb ischemia and active foot ulcer or gangrene, and compared outcomes between subgroups according to whether the centre’s management protocol (early, aggressive debridement, revascularisation with percutaneous angioplasty (PA), multiagent intravenous antibiotics, and controlled follow up) was applied in total including PA, or partially, without PA. Reasons for not including PA included severe comorbidities, the extent of the foot lesion being incompatible with limb salvage, and small lesions that showed a relatively fast evolution to spontaneous healing. The rate of major amputation was 15.7% (80/510) in the whole group, 14.7% (67/456) in the PA group, and 24.1% (13/54) in the no-PA group (Chi squared test of PA versus no-PA, p<0.0009).
Summary

The only secondary evidence source identified by the scoping literature search was an HTA published more than 10 years ago. Operational modelling using data from the 1990s showed that changes in the management of PVD in a devolved service to match the central hospital would be expected to reduce the number of major amputations and increase the proportion of more distal amputations, vascular reconstructions and angioplasties. Published observational studies dating from the 1980s and 1990s suggested an inverse association between the provision of vascular reconstruction and amputation rates. More recent observational studies from the USA suggest that there may be an association between increased use of endovascular treatment of PAD and lower rates of amputation.

A UK RCT indicated that patients with severe leg ischaemia can reasonably be treated with either open bypass surgery first or balloon angioplasty first. There is evidence from case series that increased use of revascularisation procedures, including angioplasty, reduces rates of amputation. NICE guidelines recommend that inpatients with diabetic foot problems should be managed by a multidisciplinary foot care team. There is known variation in diabetic amputation rates in England. A reduction in diabetes-related amputations over time has been observed in at least one published UK study.

Further work for Healthcare Improvement Scotland

Scoping identified a limited amount of published evidence to answer the question posed. The only evidence identified by the scoping literature search concerned the provision of vascular reconstruction surgery and the use of endovascular treatment. Apart from endovascular treatment, most of the published literature identified is more than 10 years old including the only study that modelled the expected implications of vascular services organisation on rates of amputation. The utility of an Evidence Note based on this information may be of limited relevance to current practice. A detailed review and appraisal of the published modelling study was not undertaken for this scoping report. The vascular services review steering group has indicated to the Scottish Health Technologies Group that this report is sufficient for their purposes and that it does not require Healthcare Improvement Scotland to undertake further evidence review work on this topic at this time.

Equality and Diversity

Healthcare Improvement Scotland is committed to equality and diversity in respect of the nine equality groups defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion, sex, and sexual orientation. As a scoping report summarises information and does not provide recommendations a full EQIA assessment is not deemed necessary.

The process for producing scoping reports will be assessed when available, however no adverse impacts across any of the groups is expected.

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References


