

Configuration of vascular services: a multiple methods research programme

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Scientific summary

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Scientific summary

Background

There have been extensive changes in the delivery of vascular services over the past 20 years. New technologies have been introduced that cross traditional disciplinary boundaries and a new specialty of vascular surgery has been created that deals with a range of complex and often urgent or emergency procedures. This has significant implications for workforce planning and training arrangements and has resulted in the need for service reconfiguration. The planning, monitoring and evaluation of such changes requires the availability of suitable information on the effects that this has on practice and outcomes.

Objectives

The overarching aim for the programme was to develop data sets, outcome measures and cost-effectiveness models that inform the development and evaluation of high-quality subspecialist vascular services. To achieve this, substudies were carried out to identify the features that are important to patients, clinicians and commissioners, and to address these through the use of existing or new outcome measures and through developing methods to analyse routine data sources. Further objectives of these studies were to inform the development of a new electronic tool for the collection of clinical information and patient-reported outcomes and the development of computer models that could be used to predict the effects of organisational changes.

Methods

The programme was divided into four main workstreams that were closely linked and used a range of methods.

Workstream 1: the identification of current service arrangements and analysis of Hospital Episode Statistics

Systematic literature reviews were carried out to evaluate published evidence relating to the relationship between hospital or surgeon volume of activity and outcomes for people with vascular disease. A single search strategy was developed and subsequently divided into three main areas of interest: abdominal aortic aneurysm, peripheral artery disease and carotid artery disease. Standard review methods using a published risk-of-bias tool were used following a published protocol (Phillips P, Shackley P, Kaltenthaler E, Poku E, Essat M, Woods H. *Volume-outcome Relationships in Peripheral Vascular Surgery: A Systematic Review*. PROSPERO 2014 CRD42014014850. URL: www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42014014850; accessed 1 December 2020).

An analysis of a Hospital Episode Statistics extract of linked data for all patients who had a vascular inpatient episode between 2002/3 and 2017/18 was subsequently limited to index episodes since 2008/9. The analysis included detailed mapping of data based on diagnostic, procedural and other codes to classify episodes relevant to vascular services and identify potential outcome measures, comorbidities and measures of resource use. This was carried out through an iterative process with a clinical consensus group, developing coding algorithms in R (The R Foundation for Statistical Computing, Vienna, Austria) to develop clinically meaningful categories of vascular activity and measures of outcome and to identify aspects of a service configuration, such as changes in site and travelling distance.

Further analysis compared Hospital Episode Statistics details with publications from the National Vascular Registry concerning activity and service configuration and a case study of known service reconfiguration.

Workstream 2: the identification and development of outcome measures

Systematic literature reviews assessed psychometric evidence of existing patient-reported outcome measures for conditions managed by vascular services and reviewed published qualitative research to identify aspects of vascular disease that are relevant to patients. For all systematic reviews, protocols were registered prior to their conduct. Reviews were carried out in line with the recommendations made by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis, the Oxford system and the Consensus-based Standards for the selection of health Measurement Instruments, as appropriate. For the reviews of existing outcome measures, a two-stage search procedure was developed in which preliminary searches identified potential generic and disease-specific outcome measures for each area of vascular disease and subsequent secondary searches included more detailed searching on the measures that had been identified as potentially relevant. The reviews were split into five key clinical areas: peripheral artery disease, abdominal aortic aneurysm, carotid artery disease, varicose veins and venous leg ulcers.

An electronic, web-based data collection tool for use with patients with vascular disease (the electronic Personal Assessment Questionnaire – Vascular) was developed and evaluated using an established process through four stages. In stage 1, the systematic reviews mentioned above and a primary qualitative study using semistructured interviews with patients living with a range of vascular conditions identified the main areas of quality of life affected by vascular disease and developed key themes for consideration in the electronic Personal Assessment Questionnaire – Vascular. A consensus exercise with vascular clinicians considered these initial themes and assessed their importance from the clinician's perspective. In stage 2, the evidence from the systematic reviews, qualitative study and clinicians' consensus study was used to develop the items for inclusion in the questionnaire, which were tested in a face validity exercise with clinicians and patients. In stage 3, a survey was carried out to reduce the number of items and confirm the domain structure of electronic Personal Assessment Questionnaire – Vascular. Finally, in stage 4, an additional survey was carried out to evaluate the psychometric properties of the instrument, including test-retest reliability, known groups validity and responsiveness.

Workstream 3: the evaluation of non-health service attributes

The third workstream evaluated societal preferences for aspects of service other than clinical outcomes that were important to decision-making. Two key issues were identified as important to the modelling of service configuration, the travelling distance to access vascular services and the choice between minimally invasive and open surgery, as exemplified by the difference between endovascular aneurysm repair and open surgical repair. A trade-off exercise was carried out using written scenarios describing the potential outcomes and visual aids to describe the possible choices. Participants were asked which of the specific scenarios they would prefer and an iterative process was used to establish the additional risk they would accept for their preferred option.

Workstream 4: the development of vascular service models

The modelling of vascular services was carried out by using a simulation based on three main areas of vascular disease: abdominal aortic aneurysm, carotid artery disease and peripheral artery disease. For each of these a simulation model was developed with the main inputs derived from an analysis of Hospital Episode Statistics, which were used to generate regression models to predict the hospital costs and outcomes after vascular treatment. Data that were not available from Hospital Episode Statistics were identified from additional searches of published sources. All statistical analyses were carried out in R and the simulation was also developed in R with an interactive user interface that could be deployed as a web-based application. All costs were reported in Great British pounds at 2017/18 prices, and costs and outcomes were discounted at 3.5% per year.

Results

Workstream 1

The systematic reviews of the relationship between activity and outcome suggested that increasing hospital volume was associated with reduced mortality for both carotid artery disease and abdominal aortic aneurysm repair. For peripheral artery disease, the evidence suggested that an increase in hospital volume was associated with a higher rate of repeated treatments and a lower rate of post-operative amputations.

Hospital Episode Statistics data demonstrate several trends in practice and workload. Both emergency and elective abdominal aortic aneurysm treatments are declining, with an increasing proportion of endovascular aneurysm repairs, although there is substantial regional variation in practice. Overall mortality and length of stay are declining for most patient groups. For peripheral artery disease, the number of admissions is falling, apart from minor amputations, which have increased substantially over the period of the study. There is considerable local variation, particularly in relation to the use of endovascular treatments and inpatient investigations. Carotid artery disease admissions have fallen, with an increasing proportion of emergency admissions.

Varicose vein treatments fell rapidly in 2011/12, but have subsequently increased again, with the modalities of radiofrequency ablation and endovascular laser therapy having largely replaced open surgery.

Comparisons of Hospital Episode Statistics data and National Vascular Registry publications demonstrated similar findings regarding the configuration of services but highlighted some of the potential pitfalls in the different ways in which mortality is recorded and reported and the limitations of a procedure-based registry without data linkage.

Workstream 2

The reviews of patient-reported outcome measures showed that Short Form questionnaire-36 items and EuroQol-5-Dimensions were the most widely used generic measures with some evidence of acceptability but poor evidence of responsiveness and little full psychometric evaluation. For most conditions there was an absence of well-validated disease-specific questionnaires. For varicose veins the Aberdeen Varicose Vein Questionnaire was the most extensively validated but had questionable content validity. Overall, the systematic reviews did not identify appropriate disease-specific questionnaires that were well validated and could be directly incorporated into the electronic Personal Assessment Questionnaire – Vascular.

Framework analysis on the primary qualitative data identified six overarching themes relating to the impact of the conditions. These were symptoms, impact on physical function, social impact, psychological impact, financial impact and lifestyle. These conditions were mapped and tabulated and those areas common to multiple conditions were identified. The synthesis of published qualitative data identified a number of overlapping domains and confirmed many of the findings of the primary research. The domains and themes identified from these studies were used to inform the development of the questions for the electronic Personal Assessment Questionnaire – Vascular.

The electronic Personal Assessment Questionnaire – Vascular development process used the primary qualitative and systematic review evidence to generate 168 items, of which 59 were initially eliminated because of repetition. The instrument was divided into one generic and three disease-specific sections for abdominal aortic aneurysm, carotid artery disease and lower limb conditions, and grouped across eight scales. These were assessed for usability, accessibility and appropriateness. Confirmatory factor analysis using data from 628 patients revealed eight distinct scales and the results were used to reduce the items that exhibited local dependence. A second quantitative survey, carried out in a sample of 721 patients with a range of vascular conditions, was used to further evaluate the psychometric properties of the 55-item electronic Personal Assessment Questionnaire – Vascular. The results

showed good known group validity in line with prespecified hypotheses, acceptable test-retest reliability ($n = 181$) and good responsiveness ($n = 55$) with moderate to large effect sizes.

Workstream 3

For the study of process utilities relating to abdominal aortic aneurysm repair, a total of 209 participants were recruited and overall results suggested that a majority would prefer endovascular aneurysm repair and would be prepared to trade expected quality-adjusted life-years for the less invasive process. Those who were willing to trade were estimated to be willing to give up, on average, 0.135 expected quality-adjusted life-years for the preferred treatment.

For the questions relating to location of services, a total of 608 patients were recruited across the three diagnostic areas of abdominal aortic aneurysm, carotid artery disease and peripheral artery disease. In summary, for the various scenarios the results showed that 55.5–66.2% would require some compensation for increased travel distance. For example, the magnitude of the required compensation for travelling an additional 30 miles ranged from 0.2 quality-adjusted life-years for carotid artery disease treatment to 0.63 quality-adjusted life-years for peripheral artery disease.

Workstream 4

Three separate simulation models were developed for abdominal aortic aneurysm, carotid artery disease and peripheral artery disease. These were combined to develop a single holistic model to simulate previous, current and predicted activity, costs, resource use and outcomes for any subset of hospital sites in England. The model allows various assumptions and configurations to be chosen via a web-based interface and will provide predicted results with the overall workload and outcome estimates and evaluation of the cost-effectiveness for the chosen models of configuration.

The model performance was validated through comparison of the simulated and actual data and by comparing actual and predicted effects of known reconfigurations, during the period for which Hospital Episode Statistics data were available. In both of these investigations, the model performed well.

Conclusions

The programme of research has developed a broad range of evidence regarding the current arrangements of vascular services, the nature and quality of current outcome measures and the current trends and variation in practice that relate to particular aspects of service configuration. The programme has gone on to develop two major tools that may be of value in planning, delivering and evaluating future vascular services. The electronic Personal Assessment Questionnaire – Vascular is a web-based tool for the collection and evaluation of patient-reported outcome measures and other information of relevance to clinical management and service evaluation. The second is a web-based simulation model that predicts the effects of service reconfiguration.

The data analysis suggests that there is considerable variation in practice with regard to vascular services, with variable uptake of new technologies, such as the use of minimally invasive treatment for abdominal aortic aneurysm and peripheral artery disease, and new modalities for the treatment of varicose veins. In addition, there is confirmatory evidence of the potential benefits of service reconfiguration to create larger centres with the critical mass and volume of activity necessary to achieve optimum results. Although the recommendations of the NHS service specification and the provision of vascular services document suggest that centres should be large enough to carry out a minimum of 60 aneurysm procedures per year, the evidence from the analysis suggests that further gains may be achieved by increasing this threshold further to levels of around 100 cases per year. The analysis of activity data suggests that, although some smaller centres have merged to attain the necessary activity levels, there remain many areas in which further gains may be achieved by similar reconfiguration.

One of the main limitations of the study is the nature of the data available for the evaluation of services. One key implication for the delivery of high-quality services is that there is an urgent need to develop systems that allow the collection of richer clinical data and its linkage to administrative data sets. Although the National Vascular Registry is collecting high-quality clinical information, this is a procedure-based registry relating to a number of selected procedures. Data attainment is incomplete and the lack of linkage to administrative data sets means that it is not possible to obtain clear follow-up information regarding repeat procedures, re-admissions, late complications or mortality.

Another key implication of the research findings is the need for individual regions to consider options for reconfiguration, where small units continue to offer services that are below the recommended threshold for activity level, and to identify the existing barriers to reconfiguration. Improvements in cost-effectiveness that may be attained by reconfiguration need to be considered in the context of evidence for strong preferences for local treatments. The results suggest that there may be considerable opportunity for more integrated services in which major vascular procedures are carried out at a single site, but collaborative working arrangements allow those patients who can safely be treated with minor procedures, investigations or rehabilitation services, to be managed at a more local site.

In terms of recommendations for further research, the electronic Personal Assessment Questionnaire – Vascular tool has been developed and shown to have good psychometric properties. However, further work is required to evaluate its usefulness in wider clinical practice and its potential for monitoring service outcomes.

A second research recommendation relates to the linkage of clinical data from the National Vascular Registry and routinely collected patient-reported outcome measures to administrative data from Hospital Episode Statistics to attain a more accurate picture of clinical outcomes, resource use and patient pathways.

Study registration

This study is registered as PROSPERO CRD42016042570, CRD42016042573, CRD42016042574, CRD42016042576, CRD42016042575, CRD42014014850, CRD42015023877 and CRD42015024820.

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