The failure of evidence-based guidance: A review of the implementation of national guidelines in vascular services

A report based upon an analysis of trends and disparities in the provision of vascular services, carried out as part of an NIHR programme of research by the Vascular Services Research Group at the School of Health and Related Research, University of Sheffield.

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Executive summary

Introduction

The Vascular Services Research Group at the School of Health and Related Research (ScHARR), University of Sheffield, along with several academic and clinical partners, has been at the forefront of research into the provision, effectiveness, and cost effectiveness of vascular services. In recent years, an extensive NIHR funded programme of research has considered trends and variation in vascular services in England, particularly in relation to socioeconomic, demographic, ethnic and geographical disparities in service provision and outcomes. This report pulls together the evidence that has demonstrated marked variation in the implementation of national evidence-based guidance, examines potential reasons for this variation, and makes recommendations regarding the development and implementation of such guidance in order to improve implementation.

Background and Relevant Guidance

Vascular services deal with several serious, often urgent, and potentially life or limb-threatening conditions, including limb-threatening ischaemia, abdominal aortic aneurysm, and carotid artery disease. Specialised vascular services have been a rapidly developing area of healthcare, with subspecialisation within many disciplines, including surgery, interventional radiology, specialist nursing and medical physics. New diagnostic and treatment modalities, particularly minimally invasive techniques, and changes in organisational and funding arrangements have had a major impact on services.

Several bodies provide national evidence-based guidance that is relevant to the provision and delivery of vascular services. This report focusses on specific recommendations where marked disparities, or apparent deviation from guidance, has been identified. These include service reconfiguration (National Service Specification and VSGBI Provision of Vascular Services document), the use of endovascular aneurysm repair for infrarenal and complex abdominal aortic aneurysm (NICE appraisal and guidelines and NHS England commissioning policy), the availability of supervised exercise for intermittent claudication and the management of chronic limb threatening ischaemia (NICE guideline), the surgical management of carotid disease (NICE guideline) and the treatment of varicose veins (NICE guideline). In all these cases there was evidence of services and practices that are subject to marked geographical variation and, in places, are contrary to the guideline recommendations. Apparent reasons for deviance from guidance includes divergent patient and clinician choices, lack of appropriate facilities or services, and local commissioning policies that contradicted the guidance.

Factors contributing to poor implementation of guidance

Five key problem areas have been identified as contributing to the incomplete implementation of national guidance.

1. *Conflicting objectives*

Those developing the guidance may have different objectives to those implementing them. NICE guidelines claim to support shared decision making. However, a key objective is obtaining value for money, whereas individual professionals and patients, in a publicly funded or insurance-based healthcare system, may make decisions that maximise clinical effectiveness rather than cost effectiveness. Other conflicting objectives may relate to cost containment, professional standards that may encourage defensive practice, and workforce management, such as meeting working hours directives.

2. *Conflicting values and preferences*

Guidance, by its nature, must be generalisable and will use average societal or consensus values and preferences for the trade-offs between different dimensions of health and other factors. Where professionals and patients have the flexibility to override such guidance in individual decisions, it is likely that they will use their own values and preferences in such trade-offs.

3. *Lack of personalisation*

The generic nature of guidance may fail to consider the potential for individual circumstances in which demographic, anatomical, or physiological risk factors, or personal values and preferences, would lead to different decisions. Although more nuanced guidance, based upon subgroups, may be possible, this is limited by the available evidence, difficulty in implementation and the potential for discriminatory guidance.

4. *Failure of implementation*

Implementation may fail due to a lack of adequate dissemination of the guidance or lack of appropriate mechanisms for driving and monitoring compliance. Where implementation is through commissioning or purchasing arrangements, failure may result from a lack of adequately detailed data to monitor compliance, particularly where detail is required to determine appropriate eligibility or selection criteria.

5. *Perverse incentives*

There are many potential perverse incentives that can undermine the implementation of guidance. These include financial, academic, professional, and commercial influences, including commissioning arrangements, private practice, professional standards, industry marketing, and incentives to participate in commercial 'seeding studies'.

Recommendations

The following are suggestions relating to the development, presentation, implementation, and monitoring of guidance.

1. All guidance should be clear about the objective of the recommendations provided and the perspective from which they have been developed (societal or individual).
2. Wherever possible, recommendations based upon different objectives or perspectives should be documented separately or, as a minimum, clearly identified as such.
3. Recommendations that are aimed at meeting societal objectives, such as equity and value-for-money, should be implemented through purchasing arrangements, professional standards, or regulatory mechanisms.
4. Healthcare professionals should not be placed in the position of enforcing recommendations that are based upon societal objectives, where these conflict with the most effective treatment for the individual, patient choice, or personal preferences.
5. Where recommendations aim to achieve equity, value for money or other societal objectives, but apply only to a subgroup of eligible patients, there needs to be a clearly identified and adequate mechanism for equitable implementation that includes:
    a. Measurable and enforceable criteria for eligibility
    b. Mechanisms for prior approval of eligible cases or retrospective data collection to enable commissioners, rather than individual clinicians, to take responsibility for ensuring compliance.
    c. The costs and resource implications of any additional data collection and analysis should be included in calculations of cost effectiveness and the decision-making process.
6. Where additional data collection is required to monitor adherence to guidance, this should be fit for purpose, collecting the relevant data for all potentially eligible patients, including those who may be excluded from intervention.
7. Where guidance aims at supporting individuals in shared decision making, recommendations should include factors that may be relevant to personalisation, such as personal risk factors, individual preferences, and disaggregated outcomes, using risk models and decision aids, as appropriate.
8. Where service developments are recommended that require additional investment, consideration should be given to mechanisms for funding this or diverting the resources through linked disinvestments, or the use of ring-fenced budgets.

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Introduction

Over the past few decades there have been significant changes in the organisation and delivery of vascular services, which have emerged as a new specialist area requiring input from many disciplines. [1] Vascular surgery has separated from general surgery with separate training and accreditation, and vascular interventions available to interventional radiology have developed rapidly. New technologies have been developed for treating many conditions, including aneurysms, peripheral arterial disease, and varicose veins.

For the past twenty-five years, the Vascular Services Research Group at the School of Health and Related Research (ScHARR), University of Sheffield, along with several academic and clinical partners, has been at the forefront of research into the provision, effectiveness, and cost effectiveness of vascular services. This has included studies of both the clinical effectiveness and cost effectiveness of new technologies for treating vascular disease [2-8], analysis and modelling relating to the organisation and provision of services [1, 9] and patient focussed studies relating to outcome measurement and patient preferences. [10, 11]

Most recently, the group has undertaken a six-year programme of NIHR funded research around the configuration of services [1] and is currently undertaking further work as part of a Programme Development Grant to consider socioeconomic, demographic, ethnic and geographical disparities in service provision (for further details see: https://fundingawards.nihr.ac.uk/award/NIHR202042).

Initial consideration of geographical disparities has suggested substantial regional and local differences in the implementation of national guidance in respect to the provision of vascular services and the management of specific conditions. [1] Many of these have been subject to the development of clinical guidelines by NICE or national guidance by other authorities (see Appendix 1). Such guidance includes the Service Specification for Adult Vascular Services developed by the Clinical Reference Group of NHS England, Provision of Vascular Services guidance produced by national professional bodies, and guidelines produced by NICE for varicose veins (CG168), peripheral arterial disease (CG147), stroke (NG128) and abdominal aortic aneurysm (NG156). As an example, work that has recently been published shows very marked regional variation in access and treatment policies regarding varicose veins, which do not appear to comply with the NICE guideline that was introduced in 2013. [12, 13]

This discussion paper provides a review of the relevant national guidance relating to the provision and nature of vascular services, consideration of the existing evidence from published and available routine data sources that relate to the implementation of such guidance, and identification of relevant factors that may act as drivers or barriers to implementation.

The paper is divided into **three sections**. The **first section** describes the background and context regarding the nature, development and current configuration of vascular services, the commissioning arrangements, and the various sources of guidance.

The **second section** deals with some examples of the specific organisational, diagnostic, and procedural areas that have been subject to guidance, reviewing the relevant recommendations, particularly those that would require a change in services or practice. It considers the evidence relating to compliance, non-compliance, and disparities in each area of practice, and the drivers and barriers to implementation of the recommendations.

The **third section** examines general issues around the development and implementation of guidance. It considers the perspectives of different stakeholders in the delivery of services, including service providers, commissioners, service users and those representing political or industry interests. It assesses the importance of the differing criteria underlying recommendations, including clinical effectiveness and cost effectiveness, cost

containment and the various measures of success or outcome that may be relevant to stakeholders. Finally, it makes suggestions and recommendations relevant to the development and implementation of future guidance.

Section 1 – Background

The nature and development of vascular services

Specialised vascular services are provided by physicians, surgeons, and interventional radiologists as well as a range of specialists within allied professions, including clinical nurse specialists, medical physicists, and physiotherapists. They deal with diseases of the circulation (arteries, veins, and lymphatics), other than the heart and other vessels within the chest, which are largely within the domain of cardiothoracic surgeons and cardiologists. They are also, increasingly, providing support for cardiovascular and neurovascular interventions and trauma services.

About 90% of the services provided relate to four groups of clinical conditions: -

- Abdominal aortic aneurysm (AAA) is a dilated area on the main artery in the abdomen that can rupture if untreated.
- Peripheral arterial disease (PAD), in which the circulation to the legs is impaired, resulting in pain on exercise (intermittent claudication) or in more severe cases (chronic limb threatening ischaemia) may lead to pain at rest, ulceration, gangrene, and the need for leg amputation.
- Carotid artery disease (CAD), with narrowing of the arteries in the neck giving rise to a risk of stroke.
- Varicose veins (VV) and their complications.

In addition, there are several, less common conditions, affecting circulation to the arms or within the abdomen, and others that may be jointly treated with other disciplines, such as major trauma, providing vascular access for cancer treatments or dialysis, and joint working with diabetologists and cardiothoracic services.

Vascular services emerged as a separate specialist area in the 1990's, largely from subspecialisation within general surgery, but with increasing links to interventional radiology and other specialties. In 2012 Vascular Surgery became recognised as a separate specialty with its own training and accreditation. Alongside this, advances in technology, particularly for minimally invasive treatments, have led to sub-specialisation in vascular interventional radiology.

Organisational and commissioning arrangements

Vascular services provide a range of major, specialist and frequently urgent treatments for conditions that cause an imminent risk to life or limb, such as abdominal aortic aneurysm and chronic limb threatening ischaemia. They also provide treatments for minor and less urgent conditions, such as varicose veins. Since 2013 specialist vascular services (excluding varicose veins) have been commissioned though NHS England based upon a National Service Specification, whereas other conditions, including varicose veins, were commissioned by Clinical Commissioning Groups (CCGs) until their role was taken over by the new integrated care systems in July 2022.

In recent years a combination of workforce consideration and increasing evidence of the improved outcomes achieved by centres carrying out higher volumes of major vascular procedures, have resulted in moves towards centralisation of vascular services. There have also been many local service reviews, some leading to the reconfiguration of services.

Sources of guidance

There are several bodies providing national guidance relating to healthcare services that are relevant to the provision and delivery of vascular services. As described above, NHS

England is responsible for commissioning specialist services in England, and has produced a National Service Specification and one other commissioning policy, relating to complex endovascular stent grafts in abdominal aortic aneurysm. [14]

Most of the relevant guidance has been produced by the National Institute of Health and Care Excellence (NICE), which was established as the National Institute for Clinical Excellence in 2001 to provide evidence-based guidance to the NHS. In 2013 it became a non-departmental public body, responsible for producing guidance for the social care sector as well as health. It produces various forms of guidance that are relevant to vascular services.

Interventional Procedures Guidance considers whether procedures used for diagnosis and treatment are sufficiently safe and effective for use in the NHS. This guidance does not formally consider comparisons with other treatments but will determine whether a procedure should be considered an option without any special arrangements, whether special provision should be made, such as particular emphasis on the need for specific consent that takes account of uncertainty around the procedure, whether it should only be used in research, or should not be available at all. Such guidance is not mandatory.

Technology appraisals consider the clinical effectiveness and cost effectiveness of new and existing medicines and other treatments for use within the NHS. They may examine individual technologies (single technology appraisal) or multiple technologies or clinical situations (multiple technology appraisal). Technologies may be recommended as an option, recommended under specific circumstances, restricted to research, or not recommended. This guidance is mandatory in that, where technologies are recommended for a given situation, the NHS is obliged to fund the treatment if a clinician considers it is appropriate.

NICE guidelines offer wide-ranging guidance that covers multiple questions relating to a particular clinical topic. They consider both clinical effectiveness and cost effectiveness and may make a series of recommendations based upon an appraisal of the evidence by a multi-disciplinary committee, followed by public consultation. Such guidance is not mandatory.

NICE also produces other forms of guidance, such as those relating to highly specialised technologies and diagnostics.

The Healthcare Quality Improvement Partnership (HQIP) is an independent charity which works with professional societies, particularly the Vascular Society of Great Britain and Ireland (VSGBI), through the Vascular Services Quality Improvement Programme (VSQIP) to deliver the National Vascular Registry (NVR) report and recommendations. The VSGBI also produces other professional guidance, including several iterations of guidance on the Provision of Vascular Services.

Other organisations that have been involved in or produced their own guidance that may be relevant to vascular services include other professional bodies, such as the British Society of Interventional Radiology, the Vascular Anaesthesia Society of Great Britain and Ireland, the Society for Vascular Technology, National Confidential Enquiry into Patient Outcome and Death (NCEPOD), Medicines and Healthcare Products Regulatory Agency (MHRA) and Getting It Right First Time (GIRFT).

Section 2 – Specific Guidance Areas

This section considers several clinical areas where guidance has been issued, describes the main recommendations, and considers evidence from our own analysis and other sources regarding compliance with the guidance. The key subject areas considered are service configuration, AAA, PAD (both intermittent claudication and chronic limb threatening ischaemia), CAD and VVs. The specific sources of guidance that are discussed, and links to the relevant documents, are provided in Table 1. For each subject area, examples of the major recommendations that have been controversial or that might be expected to have a significant influence of clinical practice have been identified and explored further.

Service configuration

Workforce changes, rapidly advancing technology, and the introduction of a new specialty, have led to a need for changes in the configuration of vascular services. Mounting evidence has also demonstrated that more favourable outcomes are achieved when major vascular procedures, particularly aortic aneurysm repair and carotid endarterectomy, are carried out in specialist centres with higher procedure volumes.

Evidence-based guidelines for the configuration of vascular services were published by the VSGBI in 2012 as the Provision of Vascular Services (POVS), [15] and have been revised in three further editions, most recently in 2021. [16] NHS England also issued an evidence-based service specification for specialist vascular services in 2013. [14] These documents provide recommendations for the configuration of vascular services, particularly the need for centralisation of services to provide sufficient resources to deliver a full emergency and elective service with a high enough volume to ensure adequate experience and justify the workforce required to provide 24/7 cover. The recommendation is for specialist vascular services covering a population of at least 800,000, with a minimum of eight surgeons and interventional radiologists, and in 2013 the service specification specified a minimum workload of 60 AAA repairs and 50 carotid procedures. The POVS document in 2015 suggested 60 AAA and 40 carotid cases, the latter reducing to 35 in the 2021 edition. Several other recommendations cover aspects such as the facilities that should be available, multi-disciplinary team working and linkages to other services.

While the evidence for the link between volume and outcome is strong, the threshold number of cases and the exact cases to be included are questionable. [17] There is evidence that outcomes for AAA improve beyond the level of 60 per year, suggested in the guidance. [18] In addition, the introduction of endovascular repair (see below) has meant that there are considerably lower volumes of open procedures in many centres, and it is not clear the extent to which the improvement in outcome with higher volumes is transferable between different treatment modalities. [18] The 2021 revision of the POVS document suggests that the number of open elective cases should also be specified, suggesting a minimum of 13 cases per year. [16]

Over the past twenty years the number of centres offering major vascular procedures in England has reduced substantially, the number offering AAA repair almost halving between 2006/7 and 2017/18 from 136 to 69. However, most of this reduction was the result of centres with very low volumes ceasing the procedure completely and occurred prior to the first guidance in 2013. Since then, the number undertaking fewer than sixty procedures has remained static until the past few years when some have dropped below the threshold due to an overall reduction in the number of AAA procedures. [1] In the most recent NVR report, just over half of Trusts in England reporting AAA procedures carried out 60 or more procedures. [19]

Similarly, over a third of trusts undertaking carotid procedures, carried out fewer than the 40 recommended in the 2015 POVS document, a figure that has remained stable over the past few years. [1, 19]

In respect to the other recommendations of the POVS document and service specification, many of the details of suggested resources and infrastructure are not easily available. However, in terms of staffing, over 40% of vascular surgeons work in services that have fewer than the recommended eight surgeons, with 10% having five or fewer, and 45% of trusts have no access to an out-of-hours interventional radiology service. [20]

Abdominal aortic aneurysm

Abdominal aortic aneurysm (AAA) is a condition in which there is dilatation of the main artery in the abdomen. This is often asymptomatic and, if unidentified and untreated, can cause sudden and catastrophic internal bleeding with a high risk of death. In recent years a screening programme has been introduced for men aged 65 years. This has resulted in the identification of people with enlarged arteries at an earlier stage, which can then be repeatedly scanned in a surveillance programme and treated if it reaches a size that is considered to present a significant risk.

A major development in the treatment of AAA has been the introduction of endovascular aneurysm repair (EVAR), a method of treating the aneurysm with a stent-graft that is inserted through the vessels in the groin, avoiding the need for a major abdominal operation. Additional modifications of this technique have been developed for situations where a standard procedure is not possible due to the anatomy of the AAA and/or the involvement of other arteries in the abdomen, particularly those to the kidneys.

The various procedures for EVAR have been considered in several different guidelines. These include NICE interventional procedures guidance (IPG) in 2003 and 2006, a NICE technology appraisal in 2009, a NICE clinical guideline in 2020 and a clinical commissioning policy for complex stent grafts in 2013. The guidance regarding the introduction and use of EVAR and complex EVAR provides an instructive case study regarding some of the issues around the development and implementation of evidence-based guidance.

EVAR was introduced and evaluated in several randomised controlled trials in the early 2000's, particularly the EVAR 1 [21] and EVAR 2 [22] trials in the UK, and the DREAM trial, [23] ACE [24] and OVER [25]. Subsequently, 10-year and 15-year follow-up results have been published as well as an individual patient meta-analysis of the long-term results from all four trials. [26, 27] In relation to standard EVAR, the IPG in 2006 considered that the evidence "…appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit, and clinical governance".

In 2009 a technology appraisal was carried out, which involved manufacturers' submissions and an independent assessment report. The recommendations are shown in Box 1. The committee considerations on the economic evidence make interesting reading. The independent assessment group had reviewed all the available evidence and carried out economic modelling, stratifying the decision by age, aneurysm size and fitness. For most groups EVAR was not considered cost effective and, in some groups, was dominated by open surgery.

The committee decided that they could not identify objective grounds for stratification in clinical practice, so considered the whole cohort, without subgroups. The ICER for the full cohort was £122,000 per QALY, but after altering parameters, on the advice of the expert clinicians and industry, reduced the average ICER to below the threshold of £20,000 per QALY, resulting in recommendations that gave clinicians discretion regarding the use of EVAR.

Box 1

Endovascular stent–grafts for the treatment of abdominal aortic aneurysms (TA167)

1.1 Endovascular stent–grafts are recommended as a treatment option for patients with unruptured infra-renal abdominal aortic aneurysms, for whom surgical intervention (open surgical repair or endovascular aneurysm repair) is considered appropriate.

1.2 The decision on whether endovascular aneurysm repair is preferred over open surgical repair should be made jointly by the patient and their clinician after assessment of a number of factors including:

- aneurysm size and morphology
- patient age, general life expectancy and fitness for open surgery
- the short- and long-term benefits and risks of the procedures including aneurysm related mortality and operative mortality.

1.3 Endovascular aneurysm repair should only be performed in specialist centres by clinical teams experienced in the management of abdominal aortic aneurysms. The teams should have appropriate expertise in all aspects of patient assessment and the use of endovascular aortic stent–grafts.

1.4 Endovascular aortic stent–grafts are not recommended for patients with ruptured aneurysms except in the context of research. Given the difficulties of conducting randomised controlled trials, it is recommended that data should be collected through existing registries to enable further research.

In 2015 NICE consulted on a draft scope for a clinical guideline on the diagnosis and management of aortic aneurysm, with the expectation that it would include and update to the recommendations of the 2009 technology appraisal. Between November 2015 and January 2018, a guideline development committee undertook a full appraisal of the evidence, supported by extensive literature reviews and modelling by the technical team at NICE. The modelling again suggested, based upon updated evidence, that EVAR was not cost effective and draft guideline was issued for consultation in May 2018, with the main recommendations relating to the use of EVAR as shown in Box 2.

Box 2

Repairing unruptured aneurysms (Draft guideline 2018 – NG156)

1.5.1 Consider aneurysm repair for people with an unruptured abdominal aortic aneurysm (AAA), if it is:

- symptomatic
- asymptomatic and 5.5 cm or larger
- asymptomatic, larger than 4.0 cm and has grown by more than 1 cm in 1 year.

1.5.2 For people with unruptured AAAs meeting the criteria in 1.5.1, offer open surgical repair unless there are anaesthetic or medical contraindications.

1.5.3 Do not offer endovascular repair (EVAR) to people with an unruptured infrarenal AAA if open surgical repair is suitable.

1.5.4 Do not offer EVAR to people with an unruptured infrarenal AAA if open surgical repair is unsuitable because of their anaesthetic and medical condition.

1.5.5 Do not offer complex EVAR to people with an unruptured AAA if open surgical repair is a suitable option, except as part of a randomised controlled trial comparing complex EVAR with open surgical repair.

1.5.6 Do not offer complex EVAR to people with an unruptured AAA if open surgical repair is unsuitable because of their anaesthetic and medical condition.

The draft guidance caused considerable controversy and additional evidence was submitted as part of the consultation. As a result, revised modelling was carried out, which confirmed the findings in relation to the cost effectiveness of EVAR. After considerable delays the final guideline was issued in March 2020 (just after the first lockdown due to the pandemic) with the recommendations shown in the box below. These had been revised by the NICE Board (see Box 3) and was followed by a public statement from the Guideline Development Committee (Box 4). In the rationale for these recommendations NICE agreed that in most cases open repair should be preferred as the more clinically effective and/or cost-effective option but followed this by a statement that "*… NICE also acknowledged stakeholder comments highlighting the importance of individualised care. For some people, EVAR may be appropriate.*" They went on the state that; -

"In light of the evidence reviewed, practice needs to be rebalanced towards open surgical repair for infrarenal aneurysms. The recommendations will minimise harm by reducing long-term mortality and the need for re-intervention as a result of the problems with EVAR. The reduction in EVAR, and so EVAR-related re-interventions, will result in significant cost savings for the NHS.

Box 3

Repairing unruptured aneurysms (Final guideline 2020 – NG156)

1.5.3 Offer open surgical repair for people with unruptured AAAs meeting the criteria in recommendation 1.5.1, unless it is contraindicated because of their abdominal copathology, anaesthetic risks, and/or medical comorbidities.

1.5.4 Consider endovascular aneurysm repair (EVAR) for people with unruptured AAAs who meet the criteria in recommendation 1.5.1 and who have abdominal copathology, such as a hostile abdomen, horseshoe kidney or a stoma, or other considerations, specific to and discussed with the person, that may make EVAR the preferred option.

1.5.5 Consider EVAR or conservative management for people with unruptured AAAs meeting the criteria in recommendation 1.5.1 who have anaesthetic risks and/or medical comorbidities that would contraindicate open surgical repair.

Box 4

NICE guideline NG156 – statement by GDC

The GDC has the very highest regard for the NICE technical team and its excellent analysis which, in the unanimous opinion of the GDC, clearly shows that in:

1) almost all people with unruptured AAA who are fit for open surgical repair (OSR), OSR will result in a better clinical outcome and cost less than endovascular aneurysm repair (EVAR)
2) many (probably the majority) of those people with unruptured AAA who are not fit for OSR, EVAR is neither a clinically-effective nor cost-effective intervention

The GDC is therefore disappointed that the NICE Executive Board have chosen to write and publish recommendations in Section 1.5 that in the unanimous opinion of the GDC:

3) do not accurately reflect NICE's own technical analysis
4) are not concordant with NICE's own polices as set out in its Social Value Judgements and other published documentation
5) do not accurately reflect the many discussions held between NICE and the GDC in the course of numerous meetings
6) do not reflect the views of the professional or lay members the GDC
7) and which, as worded by the NICE Executive Board, endorse the continuation of non-evidence-based, clinically and cost-ineffective practice that:
    - has the potential to put people with unruptured AAA at risk of avoidable harm
    - will result in the continued mis-allocation of NHS resources

Looking at the use of EVAR in relation to the various guidance that has been published, the guidance appears to have had little impact. Following the early results of the randomised trials EVAR was taken up rapidly and, by the time of the technology appraisal in 2009 already accounted for over 50% of elective infra-renal repairs. Usage continued to rise, levelling off around a peak of 70% in 2016 and then dropping back to about 60% over the next few years. The 2021 NVR report suggested; - "*The reasons for this change could be a more conservative approach to treatment (particularly in older, sicker patients) and the influence of the draft NICE guidance, which recommended open repair more strongly than an endovascular approach."* However, the fall appears to precede the draft guidance and may, at least in part, relate to the publication of the long-term results and meta-analysis of the earlier randomised trials. [27]

Data from NHS Digital suggest that the proportion of infra-renal AAA repairs that are EVAR procedures subsequently increased to over 70%, despite the suggestion in the NICE guidance that significant rebalancing towards open repair is appropriate. This may have partly related to a preference for EVAR, to avoid major surgery during Covid, but remains at above 60% of elective cases in the most recent NVR data. [19]

A further consideration is the regional and local variation in the use of different techniques. The most recent NVR annual report shows that some individual providers select EVAR for over 90% of cases, while for others, it is undertaken in around 30% of cases. [19, 28] There are several potential explanations for such variation. Although there may be some regional, socioeconomic, and ethnic factors that result in local differences in the characteristics of patients, these are not sufficient to explain such discrepancies. [19] An alternative relates to selective referral or tertiary transfer of patients for different procedures. However, this is not borne out by evidence of rates of procedures, based upon patient residence or data on tertiary referrals. [1] This makes it most likely that these discrepancies are the result of local clinician preferences, skills, and resources, that have not been influenced by the national guidance described above.

In some cases, the use of standard EVAR devices is not possible or recommended due to the anatomical features of the aneurysm. Such issues include involvement of the renal or other vessels around the neck (top end) of the aneurysm, a conical or angulated neck or thrombus in this area. Modified methods and devices have been introduced to allow these to be treated by endovascular means. These include branched and fenestrated grafts and other techniques and are collectively referred to as treatment for complex aneurysm. It should be noted that 'complex' for EVAR, is not necessarily the same as it would be for open repair. Involvement of the renal arteries increases the risk for open repair, potentially requiring a more complex procedure with a clamp above the renal vessels. However, those units reporting low levels of complex EVAR do not appear to have higher rates of complex open procedures, involving clamping above the renal vessels. [19] This may suggest that situations, such as angulation, conical neck, or thrombus, which may result in EVAR procedures being classified as complex, might otherwise have been encountered and dealt with in a standard infra-renal open repair. Such differences in classification may impede valid comparisons between centres with very different proportions of open, EVAR and complex procedures.

The NICE technology appraisal in 2009 was limited to standard EVAR, but in April 2013 NHS England issued a Clinical Commissioning Policy for Complex Endovascular Stent Graft. This policy stated that the clinical effectiveness and cost effectiveness of such devices was unknown and that the high cost of devices precludes unlimited use. The policy identified the circumstances under which such devices might be used, outside a research setting. This involved defining the patient groups, such as those of very high risk for open repair, and the characteristics of centres carrying out such procedures. Providers were expected to have a large aortic practice (typically greater than 100 procedures per year), as provider of a vascular service to a population of over 2 million people and to have an expected case load of 24-30 complex EVAR procedures per year.

The policy stated that it was due to be reviewed in April 2014 but remains on the NHS England website and does not appear to have undergone review.

The NICE guideline (NG156) included the use of complex EVAR procedures. The draft guidance (Box 2) followed the economic analysis in suggesting that complex EVAR should only be used in the context of a clinical trial. Following consultation, the NICE Board again overruled the guideline committee and published the guidance shown in Box 5.

Again, despite the rationale for their recommendations confirming that the procedure was unlikely to be cost effective, NICE appears to have relaxed the guidance based upon stakeholder comments "*highlighting the importance of individualised care*".

Data from the NVR suggest that there has been an increasing number of complex EVAR cases since they have been separately reported, in 2015, with little evidence of centralisation in a small number of specialist units, as specified in the commissioning policy. In the most recent NVR report, of 45 units carrying out complex EVAR, fewer than half carried out more than 10 per year. [19]

Box 5

Complex endovascular aneurysm repair (Final guideline 2020 – NG156)

1.5.6 If open surgical repair and complex EVAR are both suitable options, only consider complex EVAR if:

- the following has been discussed with the person:
  - the risks of complex EVAR compared with the risks of open surgical repair
  - the uncertainties around whether complex EVAR improves perioperative survival or long-term outcomes, when compared with open surgical repair
- it will be performed with special arrangements for consent and for audit and research that will determine the clinical and cost effectiveness of complex EVAR when compared with open surgical repair, and all patients are entered onto the National Vascular Registry.

1.5.7 For people who have anaesthetic risks and/or medical comorbidities that would contraindicate open surgical repair, only consider complex EVAR if:

- the following has been discussed with the person:
  - the risks of complex EVAR compared with the risks of conservative management
  - the uncertainties around whether complex EVAR improves perioperative survival or long-term outcomes
- it will be performed with special arrangements for consent and for audit and research that will determine the clinical and cost effectiveness of complex EVAR when compared with conservative management, and all patients are entered onto the National Vascular Registry.

There is also marked regional variation, with over a third of EVAR cases in the London region being designated as complex, compared to just over 10% in the East of England. [28] As with standard EVAR, it is difficult to explain this based upon population differences, and there are not sufficient transfers between regions to explain the discrepancies. Thus, the likely explanation would appear to be differences in clinical practice. It is also possible that cases which are being designated as 'complex' by some providers would have been treated by open repair or standard EVAR elsewhere. This warrants further investigation, as it would be likely to distort outcome comparisons, since complex cases are excluded from the published metrics used to evaluate AAA outcomes.

Intermittent claudication

Reduction in the blood supply to the legs, due to narrowed or blocked arteries, can cause pain in the leg muscles on walking, known as intermittent claudication (IC). Potential treatments for IC include medical treatments and lifestyle changes to reduce the progression of disease or relieve symptoms, and various methods to improve the circulation by unblocking or bypassing the diseased vessels. Recent developments in treatment have included several minimally invasive methods that aim to open up blocked or narrowed arteries. These include balloon angioplasty, the use of metal and drug-

eluting stents, drug coated balloons and the use of mechanical or laser technologies to remove blockages.

Of these potential treatments, percutaneous atherectomy with mechanical devices and laser atherectomy have been considered through the NICE interventional procedures programme in 2011 and 2012 respectively and drug treatments for IC were considered by NICE in a multiple technology appraisal in 2011. Laser atherectomy was considered sufficiently safe and effective for use in clinical practice, whereas the evidence for mechanical atherectomy was considered insufficient. The technology appraisal recommended that naftidrofuryl oxalate was an option for treatment and that the other drugs were not recommended.

In 2012 a NICE guideline was published, which considered several questions in relation to the management of peripheral arterial disease, with the recommendations being reviewed in 2018. The full recommendations in relation to the management of IC are shown in Box 6. In summary, NICE recommended a supervised exercise programme as first line treatment, balloon angioplasty, without primary stenting, for those requiring intervention (apart from complete aortic occlusion), surgery reserved for severe cases where angioplasty in unsuitable or fails, and drug treatment with naftidrofuryl oxalate only where exercise fails, and angioplasty is unsuitable or declined.

Box 6

Peripheral arterial disease: diagnosis and management (CG147)

1.5 Management of intermittent claudication

Supervised exercise programme

1.5.1 Offer a supervised exercise programme to all people with intermittent claudication. [2012]

1.5.2 Consider providing a supervised exercise programme for people with intermittent claudication which involves:

- 2 hours of supervised exercise a week for a 3 month period
- encouraging people to exercise to the point of maximal pain. [2012]

Angioplasty and stenting

1.5.3 Offer angioplasty for treating people with intermittent claudication only when:

- advice on the benefits of modifying risk factors has been reinforced (see the recommendation on secondary prevention of cardiovascular disease in people with peripheral arterial disease) and
- a supervised exercise programme has not led to a satisfactory improvement in symptoms and
- imaging has confirmed that angioplasty is suitable for the person. [2012]

1.5.4 Do not offer primary stent placement for treating people with intermittent claudication caused by aorto iliac disease (except complete occlusion) or femoro popliteal disease. [2012]

1.5.5 Consider primary stent placement for treating people with intermittent claudication caused by complete aorto iliac occlusion (rather than stenosis). [2012]

1.5.6 Use bare metal stents when stenting is used for treating people with intermittent claudication. [2012]

Bypass surgery and graft types

1.5.7 Offer bypass surgery for treating people with severe lifestyle limiting intermittent claudication only when:

- angioplasty has been unsuccessful or is unsuitable and
- imaging has confirmed that bypass surgery is appropriate for the person. [2012]

1.5.8 Use an autologous vein whenever possible for people with intermittent claudication having infra inguinal bypass surgery. [2012]

Naftidrofuryl oxalate

1.5.9 Consider naftidrofuryl oxalate for treating people with intermittent claudication, starting with the least costly preparation, only when:

- supervised exercise has not led to satisfactory improvement and
- the person prefers not to be referred for consideration of angioplasty or bypass surgery.

Review progress after 3–6 months and discontinue naftidrofuryl oxalate if there has been no symptomatic benefit. [2012]

Identifying the way in which clinical practice conforms to, or has been altered by, the publication of guidance is difficult in this area, for several reasons. Compliance with the recommendations cannot be judged from routinely collected data as the relevant information is not reported in sufficient detail. There is little information regarding the indications for the prescription of drugs for intermittent claudication, and the overall number of prescriptions for naftidrofuryl oxalate has changed little over the past ten years, although the other drugs referred to in the technology appraisal have declined in use (Figure 1).

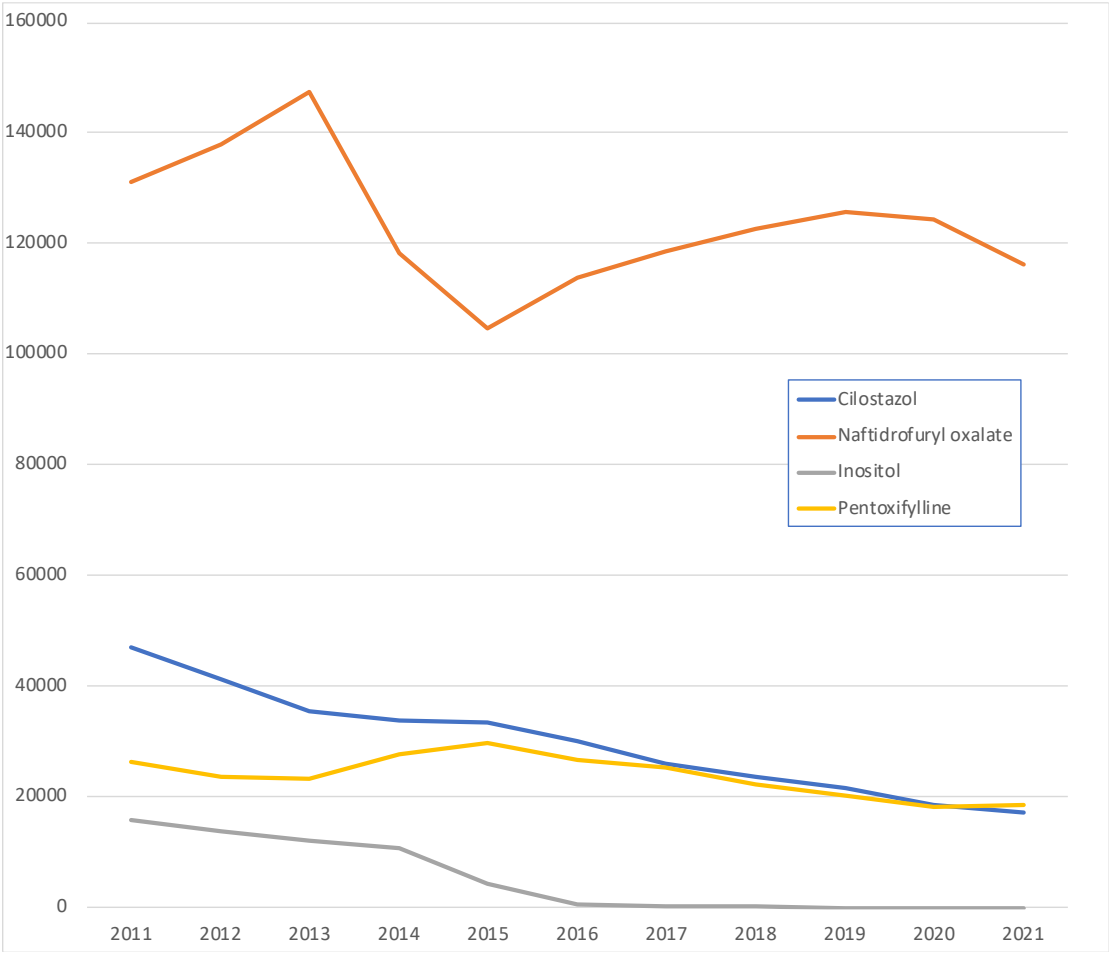

Figure 1. Usage of drugs prescribed for intermittent claudication from NHS England prescription cost analysis.

Similarly, there is no routine data regarding the availability and usage of supervised exercise. However, a published survey of vascular units in 2021 suggested that fewer than half of vascular units that responded to the survey had access to a supervised exercise programme. [29] In the case of inpatient treatment, including angioplasty, stenting and surgical bypass, the interpretation of routine data is hampered by the coding systems, with diagnostic codes failing to distinguish between intermittent claudication and chronic limb threatening ischaemia and procedural codes not separately identifying some of the newer technologies, such as drug-eluting stents (although these are separately coded for stent procedures in the coronary circulation).

Since 2014 the NVR has been collecting data on lower limb revascularisation. The information reported, for example in relation to the devices used and specific indications for procedures, is not sufficiently detailed to determine adherence to the guidance. The

data suggest considerable variation in practice as regards the use of angioplasty and bypass. However, this should be interpreted with caution as the case ascertainment is low and variable, being around 80% for surgical and 50% for endovascular procedures. [16]

Chronic limb threatening ischaemia and amputation

More severe impairment of the circulation can lead to 'chronic limb threatening ischaemia'[1], with pain in the legs at rest, leg ulcers or gangrene. The management of chronic limb threatening ischaemia and amputation have been the subject of numerous recommendations arising from the NICE guideline (CG147) in 2012, a NCEPOD report on lower limb amputation in 2014, two versions of a Quality Improvement Framework for amputation produced by the VSGBI in 2010 and 2016, a GIRFT report in 2018, and a Quality Improvement Framework for peripheral arterial disease produced by the VSGBI in 2019.

Many of the recommendations in these various reports are similar and relate to organisational aspects of the service, care pathways, multi-disciplinary working and timescales for review, investigation, and treatment. As with intermittent claudication, the routinely collected data available from NHS digital does not provide information about compliance with the recommendations. The NVR provides some information on treatments for chronic limb threatening ischaemia and amputation. It provides summaries of compliance with some of the quality standards suggested in the quality improvement framework.

The data presented in the NVR reports suggest that the standard of providing revascularisation within 5 days of admission was met in an increasing proportion of cases over the past few years, having risen to 57.8% of endovascular and 58.8% of surgical procedures in 2020. Again, there is considerable variation between providers, with just under 20% achieving the standard in over 75% of cases, and over 25% achieving it in under half of their cases. As with intermittent claudication, these reports should be treated with caution, as case ascertainment is poor in many cases. Since submission of all data to the NVR is a recommendation and quality standard, it seems unlikely that those cases submitted to NVR are a representative sample.

The NVR also reports on some of the recommendations in relation to amputation. This demonstrates similar variation between providers in terms of the delays between admission and amputation, and in the proportion of amputations that are carried out below the knee.

Carotid disease

Stroke and transient ischaemic attacks can be caused by narrowing of the arteries in the neck (carotid artery disease). Narrowing of the carotid artery can be treated by an open surgical procedure, carotid endarterectomy, or endovascular treatment with a carotid stent. NICE stroke guidance relating to the use of surgery for carotid disease was issued in 2008 [30] and substantially updated in 2019. [31] The current recommendations (Box 7) suggest urgent investigation and referral of suitable patients for consideration of surgery, although the original recommendation for surgery within two weeks appears to have been dropped. NICE interventional procedure guidance suggests that carotid stent placement is sufficiently safe and effective for clinical use without special arrangements for symptomatic, but not for asymptomatic carotid disease.

[1] Chronic limb threatening ischaemia is the current favoured term, but some papers may use the terms 'critical limb ischaemia' or 'severe limb ischaemia'.

Box 7

Stroke guidelines (NG128)

Carotid imaging

1.2.3 Everyone with TIA who after specialist assessment is considered as a candidate for carotid endarterectomy should have urgent carotid imaging. **[2008, amended 2019]**

Urgent carotid endarterectomy

1.2.4 Ensure that people with stable neurological symptoms from acute non-disabling stroke or TIA who have symptomatic carotid stenosis of 50% to 99% according to the NASCET (North American Symptomatic Carotid Endarterectomy Trial) criteria:

- *are assessed and referred urgently for carotid endarterectomy to a service following current national standards (NHS England's service specification on neurointerventional services for acute ischaemic and haemorrhagic stroke)*
- receive best medical treatment (control of blood pressure, antiplatelet agents, cholesterol lowering through diet and drugs, lifestyle advice). [2008, amended 2019]

1.2.5 Ensure that people with stable neurological symptoms from acute non-disabling stroke or TIA who have symptomatic carotid stenosis of less than 50% according to the NASCET criteria, or less than 70% according to the European Carotid Surgery Trial (ECST) criteria:

- do not have surgery
- receive best medical treatment (control of blood pressure, antiplatelet agents, cholesterol lowering through diet and drugs, lifestyle advice). [2008]

1.2.6 Ensure that carotid imaging reports clearly state which criteria (ECST or NASCET) were used when measuring the extent of carotid stenosis. [2008]

The NVR reports performance of individual providers against the 14-day criterion for the maximum delay from the onset of symptoms to treatment, with just over half of patients meeting this criterion. Again, there is considerable variation between providers, and it is notable that over a quarter of patients did not appear to meet the criterion regarding the degree of narrowing of the carotid artery. Once again, these figures may be distorted and compliance with other aspects of the guidance are not easily assessed, due to the lack of routine data. In particular, the NVR is a procedure-based registry, so the process and outcome for patients who may be suitable for such treatment and are never referred or do not undergo procedures for other reasons are not reported. Carotid stent procedures are not reported by NVR, although NHS digital data suggest that approximately 250 such procedures are carried out each year.

Varicose veins

Varicose veins of the legs are a common condition and can lead to symptoms of leg swelling, aching and treatment may be sought due to cosmetic concerns. In more advanced cases of venous insufficiency, they may be associated with skin changes, eczema, and ulceration. Leg ulceration is responsible for severe limitations in quality of life and high healthcare costs. [32] Over the past couple of decades new treatments have been developed, including endovenous ablation using laser and thermal probes and ultrasound guided foam sclerotherapy. Several of these methods have been considered in the NICE interventional procedures guidance, and in 2013 NICE published a guideline on the

diagnosis and management of varicose veins (CG168). The recommendations made in this guideline in respect to the referral and treatment of people with varicose veins are shown in Box 8.

The guidelines recommend referral to a vascular service for treatment of varicose veins for those with symptomatic varicose veins or their complications, and endothermal ablation as the first choice of treatment in those shown on investigation to have truncal reflux. As with some of the recommendations for the management of peripheral arterial disease, it is difficult to ascertain the level of compliance with this guidance from routinely collected and publicly available data as data regarding consultations for symptomatic varicose veins and the indications for treatment are not available.

Recent analysis using patient level NHS data has shown substantial variation in both the population rates, and the procedures carried out for the treatment of varicose veins. [12] These differences cannot be explained by variation in demographic, socioeconomic or ethnic factors. However, examination of documents from clinical commissioning groups shows that commissioning policy directly contradicts NICE guidance in many cases. For example, joint policy from Hampshire, Southampton, Isle of Wight CCG and Portsmouth CCG, which was issued following the NICE guidance in 2014 and has subsequently been reviewed twice, requires prior approval and limits varicose vein treatment to those with leg ulceration or bleeding. Other CCG's have issued guidance on referral policy, which varies between full implementation of NICE guidance and more restrictive arrangements. [12, 13]

Box 8

Varicose Veins guidelines (CG168)

1.2 Referral to a vascular service

1.2.1 Refer people with bleeding varicose veins to a vascular service immediately.

1.2.2 Refer people to a vascular service if they have any of the following.

- Symptomatic primary or symptomatic recurrent varicose veins. Symptomatic veins are veins found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and itching).
- Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency.
- Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence.
- A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks).
- A healed venous leg ulcer.

1.3 Assessment and treatment in a vascular service

Assessment

1.3.1 Use duplex ultrasound to confirm the diagnosis of varicose veins and the extent of truncal reflux, and to plan treatment for people with suspected primary or recurrent varicose veins.

Interventional treatment

1.3.2 For people with confirmed varicose veins and truncal reflux:

- Offer endothermal ablation (see NICE's interventional procedures guidance on radiofrequency ablation of varicose veins and endovenous laser treatment of the long saphenous vein).
- If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy (see NICE's interventional procedures guidance on ultrasound-guided foam sclerotherapy for varicose veins).
- If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.
- If incompetent varicose tributaries are to be treated, consider treating them at the same time.

1.3.3 If offering compression bandaging or hosiery for use after interventional treatment, do not use for more than 7 days.

Non-interventional treatment

1.3.4 Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

Section 3 – Discussion

The preceding section has provided several examples of national guidance that does not appear to be reflected in commissioning arrangements, service provisions or clinical practice. There are several reasons why such guidance may fail to be implemented. In this section these are considered in detail under five main headings.

1. Conflicting objectives – where the objectives of those making clinical decisions that might implement the guidance differ from the objectives that led to the development of the guidance.
2. Conflicting values – where there are value judgements and/or preferences embedded in the recommendations that do not reflect those of the individuals implementing or subject to the recommendations.
3. Lack of personalisation – where the guidelines involve a degree of generalisation which may not be seen as appropriate to the specific situation.
4. Failure of implementation – where there is a problem with the communication, dissemination, monitoring, or policing of recommendations that prevents successful implementation.
5. Perverse incentives – where there may be other influences that act as drivers for practices that do not follow the published guidance.

Each of these issues is discussed in more detail in the following sections with some suggestions regarding the implications for the development and implementation of future evidence-based guidance.

Conflicting objectives

Scientific approaches to healthcare are not new, but the last fifty years has seen a very rapid increase in scientific healthcare research, with huge expansions in the worldwide medical literature and rapidly evolving methods to identify and access relevant research outputs. Even within specialised areas relating to vascular disease, the number of annual publications may be in the thousands (Figure 2), and it is clearly not possible for individual clinicians to keep up to date with all that is relevant to their practice. The 1980's and 1990's saw the rise of systematic approaches to identifying, evaluating, and synthesising research from multiple sources to underpin 'evidence-based medicine'. Bodies such as the Cochrane Collaboration, founded in 1993 (https://www.cochrane.org), and the Centre for Evidence-Based Medicine in Oxford (https://www.cebm.ox.ac.uk), founded in 1994, were instrumental in developing methodology and promoting the publication of systematically reviewed evidence to support healthcare decisions.

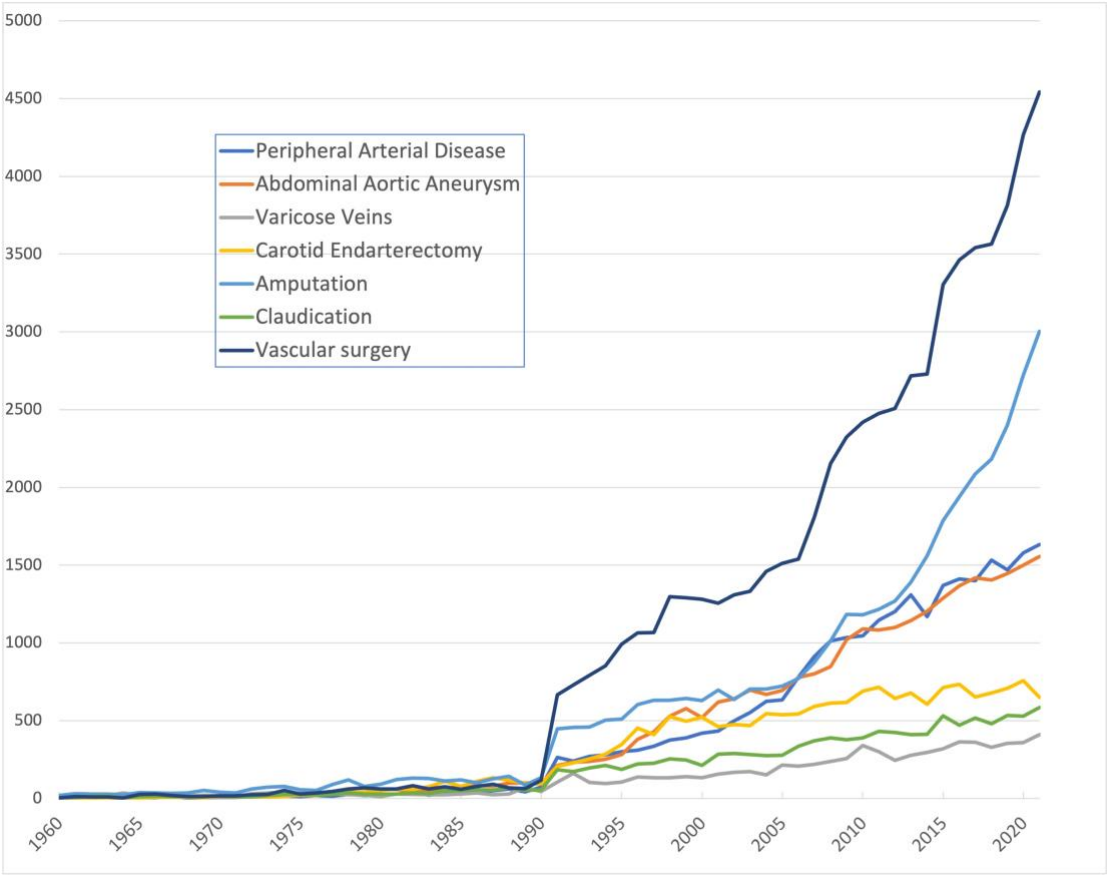

Figure 2. Number of published papers each year identified in World of Knowledge using search terms related to vascular services.

The first attempts to classify recommendations in published guidelines, based upon the strength of evidence has been attributed to the Canadian Task Force on the Periodic Health Examination. In 1979 they graded recommendations from A to E, based upon the strength of evidence to support or exclude particular interventions. [33] They also graded the strength of evidence based upon the type and quality of studies. More detailed methods for evaluation of research evidence included the development of hierarchies of evidence, [34] checklists for research quality [35, 36] and methods of combining studies through meta-analysis [37] and indirect comparisons. [38]

As the production of evidence-based guidance became more widespread, it became clear that there were factors other than the quality of evidence that influenced recommendations, and this was reflected in the development of new grading systems for recommendations in guidelines. One of the most common, and one that is preferred by several journals, and used since 2007 by NICE to separately grade the evidence and recommendations, is the GRADE system. [39] This recognises that factors, which may influence the strength of recommendations, other than the strength of evidence, include:

- the balance between desirable and undesirable effects
- uncertainty or variability in values and preferences, and
- uncertainty about whether the intervention represents a wise use of resources.

Although these might appear to be relatively minor changes in emphasis, they reflect a paradigm shift from a focus on individual patients, to a societal focus. Similar changes have been made to other grading systems, with the Canadian Task Force, for example, introducing the issues of individual preferences and values in their 2003 revisions, [40]

but then adding the societal perspective of 'whether or not the intervention represents a wise use of resources', in their current version. [41]

In evidence-based healthcare, as it was originally described, the emphasis is upon identifying the best estimates of the risks and benefits of interventions, to inform clinical decisions. David Sackett and other leading figures in the development of evidence-based medicine described it as "… the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." [42]

In the early days of evidence-based medicine, it may have been assumed that a reduction in ineffective interventions and minimising the high human and financial cost associated with ill health, would mean that the most effective care would also be the most cost effective. [43] Over the past fifty years there has been rapid development of effective interventions, inflation in healthcare costs and the diminishing returns, with the incremental costs of new treatments being out of proportion to the incremental benefits. [44] By the early 2000's it became clear that healthcare systems did not have sufficient resources for all effective healthcare and the need for rationing and emerging evidence of variation in practice [45] led to the establishment of NICE in the UK [46] and other similar bodies in other jurisdictions. [47]

The move from using evidence to inform individual clinical decisions to producing generalisable recommendations from a societal perspective, raises some potential problems that may contribute to the failure of implementation of such guidance.

The objectives of the various constituencies differ. In publicly funded or insurance-based healthcare systems, where the consumer and provider of services may be distinct from those who commission and fund services, it might be expected that the weight placed upon value-for-money will be different. Patients are likely to want the most effective treatment and healthcare practitioners will want to provide this for their individual patients, whereas commissioners are likely to take a population view to ensure the best use of available resources.

Maximising clinical effectiveness, instead of cost effectiveness, are not the only potentially conflicting objectives. Professional bodies may make recommendations that take account of workforce planning or training requirements, publication of outcomes may encourage defensive practice, and commissioners may need to make decisions on cost rather than cost-effectiveness grounds, if cost-effective interventions cannot be funded due to the difficulties in disinvestment in the less cost-effective options. Healthcare related industries, including those manufacturing drugs and medical devices, or providing healthcare services, are also involved in the development of evidence-based guidance. They are frequently responsible for generating the underlying evidence, and in some cases analysing and interpreting the evidence for submission to regulatory or other bodies, and in participating as consultees in guideline development. Their commercial objectives may influence such guidance directly or indirectly. [48]

The situation is further complicated in that some bodies, particularly NICE, produce guidance that makes recommendations based upon differing criteria. NICE interventional procedures guidance, like that produced by regulatory authorities such as MHRA, is based upon safety and efficacy. Although comparison of efficacy and safety with existing procedures is considered, the guidance does not comment on cost effectiveness and makes no judgement about whether the treatment should be provided by the NHS. Recommendations are limited to the clinical governance procedures that should be in place if the procedure is to be undertaken. In contrast, NICE technology appraisals take account of both clinical and economic evidence and makes recommendations based upon whether the technologies being evaluated are "an acceptable use of NHS resources". [49]

The situation with NICE guidelines is more complex. These frequently cover several related issues around the diagnosis and treatment of a particular condition. NICE states that the recommendations are based upon "the trade-off between the benefits and harms

of an intervention" and "the quality of the underpinning evidence". However, in practice, the scoping workshops and guideline committees develop a set of review questions to be addressed in the guideline, some of which may include issues of cost effectiveness and others may focus on clinical effectiveness, whilst wider issues such as equity considerations and practical implementation may also be taken into account in the decision making. [50]

These differing objectives may partly explain failure in the implementation of guidance. Those making clinical or policy decisions may have objectives that conflict with those embodied in the guideline. This may typically be the case where there is a conflict between a societal perspective, which considers issues such as workforce, resource use and equity, and the individual perspective, where the aim is to optimise the decision for a specific patient. NICE has attracted considerable adverse publicity [51] over some of its 'rationing' decisions, so there may be confusion and distrust of guidance if it is perceived as being based upon economic considerations rather clinical evidence.

Another potential effect of this conflict between societal and individual objectives is that healthcare professionals may find themselves in the difficult position of being encouraged or obliged, by their employer or professional body, to implement a course of action which they do not consider is in their individual patient's best interests. [52]

In the vascular conditions discussed above there are examples in which these conflicts may play a part in the lack of apparent compliance with guidance. For example, part of the reason for the continuing use of EVAR, despite the (somewhat watered-down) guidance that its use should be reduced, may be that NICE advice is seen as making its recommendations on cost grounds, so the advice against a newer and more costly treatment may be treated with suspicion, even if the evidence is that, for many people, open surgery would be preferred on clinical effectiveness grounds.

In the case of the guidance relating to intermittent claudication, the differing funding routes, and professional boundaries, relating to the provision of exercise programmes, may mean that, although these provide a clinically and cost-effective treatment option, commissioners may be unable to disinvest in existing treatments sufficiently to fund the necessary service developments.

The configuration of services creates an even more complex picture of conflicting objectives, with professional organisations concerned about workforce planning, working conditions and training demands, commissioners seeking economies of scale and cost-effective services, and patients demanding an effective, local, and accessible service. [11]

In all these cases the failure of guidance is likely to be multi-factorial and some of the other issues discussed below may also be at play.

Conflicting Values and Preferences

Despite the claims that scientific methods in evidence-based practice take an objective approach, [53] there are aspects of the process that rely upon value judgements and preferences. While the methods for research and data synthesis aim to reduce potential biases, conflicts of interest, and other potential distortions, there are many judgements that need to be made in the planning and performance of research, as well as the analysis and interpretation of results. There are choices of research question, comparators, outcomes, inclusion and exclusion criteria and analytic methods. In identifying and synthesising evidence there are choices about the criteria for considering studies to be relevant, the evaluation of study quality and the methods for interpreting and combining sources of evidence. Each of these require judgements and are potential sources of bias.

However, it is important to distinguish two different kinds of value judgement. What may be thought of as 'scientific' value judgements are those for which there is, at least in theory, an ascertainable answer. The purpose of collecting and aggregating evidence, as

described above, is to provide the best basis for making clinical decisions. The outcomes of disease and healthcare interventions are uncertain, but fully evaluating the available evidence may provide the best estimates of the likelihood of the potential consequences of a decision. Such estimates may be compared to subsequent events and future evidence for verification and modification.

A clinical diagnosis is a judgement based upon the available evidence, which may subsequently be proved right or wrong. In interpreting published evidence, the relevance of a study carried out in another country requires a judgement, which might subsequently be confirmed by further studies. In both these cases there may be a value in expertise. An experienced clinician may make a more accurate diagnosis. An epidemiologist with knowledge of international differences, or a clinician with experience of practice in the country where the research was conducted, may make a more informed judgement about the relevance of a study carried out in another country.

Making a recommendation requires an additional value judgement of another kind, that may be thought of as 'personal' value judgements. When weighing up the risks and benefits of different interventions there may be many outcomes of interest. Cochrane methods suggest that all relevant outcomes should be included in systematic reviews and each of these may be measured in different ways or at different time points. [54] The NICE methods guidance suggests that, in developing guidelines, a range of 5 to 9 relevant outcomes should be prioritised for each review question. [50] The step from evidence review to guideline recommendation requires that all the outcomes, along with any other considerations, such as cost or equity, are combined to provide what is often a binary choice, to recommend or reject a course of action in a given situation.

The weight put on any set of outcomes or considerations is not a scientific judgement. There is no 'right' answer and various stakeholders can be expected to hold different views on the balance between objectives. In making generalisable recommendations these trade-offs must be made, whether implicitly or explicitly.

In some clinical effectiveness studies and most cost effectiveness analysis, the process of merging disparate clinical outcomes is side-stepped by using a pooled metric of quality adjusted life years (QALY). The QALY combines both quality and length of survival in a measure that can, in theory, be compared across different conditions and patient groups. The quality-of-life component is derived from utility values estimated from generic measures of health-related quality of life (HRQL), such as the EQ-5D and SF36.

This does not remove the need for value judgements – health is multi-dimensional, there is both individual and collective variation in how we perceive the relative importance of pain, mobility, and social functioning, for example, or attitudes to risk and the temporal distribution of outcomes. The utility values derived from HRQL measures are based upon tariffs derived from population surveys and reflect average societal values from specific national or ethnic groups. The balance between current and future risks and benefits are adjusted based upon discount rates derived from technical economic considerations [55] but may not reflect individual attitudes to the balance between immediate risks and deferred benefits. [56]

Other considerations may be incorporated in decisions based upon the consensus of members of an 'expert advisory group'. As discussed in the previous section, there may be differing objectives that include maximising efficiency, promoting equity, workforce utilisation and libertarian considerations about individual autonomy. Balancing between these is not a calculation to which there is an objective solution, or one that can be assessed for accuracy, even with hindsight. Rather, it is a matter of personal values and preferences. Thus, the question is not 'what is the correct value', but 'whose values should be used'.

In evidence-based medicine, as it was originally described, the role of the professional is to support the patient in making the 'best' decision for them. As Eddy described it "*the*

preferences assigned to the outcomes of an intervention should reflect as accurately as possible the preferences of the people who will receive the outcomes—that is, patients". [57] The health professional may have a role in this, in helping the patient to understand the implications of outcomes with which they may be unfamiliar. This has been characterised as different doctor-patient relationships, as described by Emanuel, ranging from the informative to the paternalistic. [58] However, the underlying assumption is that the professional is attempting to approximate, represent or elicit the patient's values and preferences.

In contrast, in the preparation of guideline recommendations the individual patient's values are unknown, so the values and preferences will be those of the decision makers, expert advisory groups, policy makers, other stakeholders, or average societal estimates. In practice, some average societal values and preferences are embedded in the evidence, such as the tariffs used in estimating QALYs, some are based upon policy considerations, such as willingness to pay thresholds, and others are determined by advisory panels or consultation processes.

This may, at least in part, be responsible for the failure of many guidelines. If the values and preferences of individual patients and/or their healthcare professionals, are not reflected in the guidance then they may not be implemented. Other than differences in how the various health outcomes are valued by patients, there are other potential aspects that may well be relevant to individual decisions. Patients may have strong preferences relating to aspects of the process of care, such as location of services and continuity of care. The preference for EVAR, in situations where it would not be recommended, even on clinical effectiveness grounds, [10] may indicate a preference for the less invasive process (process utilities), attitudes to risk, and time preferences related to the trade-off between immediate procedure-related, and long-term, outcomes.

Lack of personalisation

By their nature, guideline recommendations must be generalisable. However, as discussed above, the various stakeholders may have differing objectives, values, and preferences. As a result, any recommendation may not maximise the likelihood of preferred outcomes for a particular individual. One response to this, as stated by NICE, is that their guidelines should be used as part of a shared decision-making process which "*involves choosing tests and treatments based both on evidence and on the person's individual preferences, beliefs and values"*.

There are several issues with this response.

As discussed previously, NICE, and other bodies producing guidance, may have several competing objectives including, as stated by NICE, utilitarian and egalitarian principles of "*…providing the most overall benefit for the greatest number of people*" and "*…reducing health inequalities*". For guidance that has the objective of addressing health inequalities or maximising the benefit from limited healthcare resources, recommendations based upon societal values derived from the general population or elected or representative proxies, would be appropriate. For individuals to override such guidance based on personal preferences, would be contrary to these objectives and may exacerbate inequalities and inefficiencies, particularly as it is likely that more empowered individuals would be best able to do so.

Secondly, the preferences and values that are embedded in such guidance may not be transparent, so it may be difficult for individual patients or clinicians to understand how differing preferences impact any specific recommendation. Guidance may be based upon QALY calculations, using tariffs that do not reflect personal preferences, or may use proxy or compound outcome measures that are difficult to interpret on a personal level.

Finally, there is an underlying problem with all evidence-based guidance in that the most influential evidence comes for studies that are, necessarily, aimed at providing averaged

rather than personalised, estimates of outcome. The highest level of evidence for treatment effects is generally seen as coming from randomised controlled trials. The purpose of these is to estimate average risks and benefits by comparing similar populations. Attempts may be made to ensure the groups are comparable by stratification or minimisation techniques for known risk factors. Randomisation and blinding help to avoid conscious or unconscious biases and ensure similar distribution of unknown factors that may influence outcome. Ideally, where there are known factors that may influence outcomes, subgroups may be identified within larger trials or separate trials may be carried out. However, in practice there are often commercial constraints on the size and duration of trials that make this unlikely and those who may respond differently due to age, comorbidities, or other factors, are excluded from the trials.

Due to the expected variation in overall outcomes, differences between groups are usually expressed in relative terms, as odds ratios, relative risks, or hazard ratios. These may form a reasonable basis for decision making when comparing treatments that may be expected to have similar risks and benefits in homogenous populations. However, where treatments being compared are very different in nature, such as comparing medical and surgical treatment options, it is likely that risk factors have differing impact on the treatment options. It may be possible to provide more nuanced guidance by applying evidence from risk models, subgroup analysis or meta-regression, but there are limitations in this.

- Individuals have unique risk profiles. At best, risk scores or subgroups represent simplifications and cannot account for a large potential array of anatomical, demographic, and physiological factors.
- Increasing complexity of guidance, with different recommendations for various subgroups, creates challenges for both implementation and equity (for example age, sex and ethnicity may be important determinants of outcome).
- There may be local factors that have an impact on outcome and, particularly in skills-based procedures such as surgery and interventional radiology, local outcomes may differ from national averages.
- In some situations, it is the absolute rather than relative risks and benefits that are important. This is often the case where cost effectiveness is being considered. For example, a life-saving treatment at a given cost becomes more cost effective the greater the expected survival.

The issues around the development and implementation of guidance for EVAR provides examples of some of these issues. The evidence relating to EVAR comes from several early randomised trials, which included a wide range of patients with differing anatomical, demographic, and physiological characteristics. Early results showed that, on average, EVAR was safer than the open surgical alternative, with lower early mortality and morbidity, but higher cost. [21] However, long-term results suggested higher rates of late complications and procedures, with survival curves crossing later. [59] Thus, there is a trade-off between lower procedure-related risks against better long-term outcomes and lower cost. However, several factors are likely to alter the balance of risks and benefits. Anatomical features, demographic, and health factors may have different impacts on the two treatment options. Pulmonary comorbidities and previous abdominal surgery may disproportionately influence the results of open surgery, conical aneurysm neck or thrombus may adversely affect EVAR risks. [60] Furthermore, because there is a trade-off between early complications and late survival, the absolute benefit, and therefore the cost effectiveness, is closely related age and other factors that determine overall life expectancy. [61]

Modelling some of these patient-related factors for the technology appraisal, and other subsequent modelling, has shown that, although EVAR does not appear to be cost effective *on average* there are identifiable circumstances in which it would be cost effective, based upon current thresholds, and other circumstances in which it is dominated (both less

effective and more costly). [61, 62] However, the appraisal committee, in considering the evidence, concluded that "*there were no universally accepted criteria for assessing operative risk for aneurysm surgery, the fitness and age criteria used in the original Assessment Group's economic model could not be routinely reproduced in clinical practice*. They, therefore, concluded that average figures should be used and, although the base case of the economic assessment was well above the usual threshold, they defined an 'average' patient and revised parameters in a way that brought the estimate to an acceptable level, whilst leaving it to the clinician's discretion to take other factors into account.

In the case of EVAR, the situation is further complicated by other factors and differing objectives.

- Patients may value the 'process utilities' associated with a less invasive procedure to an extent that is not recognised in the appraisal process
- Patients may have different time preferences, which put far more weight on the immediate risks compared to long term outcomes than are recognised in current discount rates
- Patients and clinicians may be drawn to new and innovative treatments, or there may be commercial drivers to adopting these.
- There may be resource implications related to the high dependency and hospital bed requirements for open surgery.

Failure of implementation

Guidelines are costly and time consuming to produce and are of little value if they fail to influence practice. There are several reasons for a failure to follow such guidance, and each has different implications for the development and implementation of such guidance. Ultimately, individual healthcare professionals and/or their patients will make decisions about how to manage any given situation. Ideally this will be through shared decision-making, although the balance of input from professional and patient will depend upon the particular circumstances and relationship.

Failure to implement guidance may result from a lack of awareness of the relevant recommendations. Although this may be a contributory factor in some cases, it seems unlikely that professionals in a specialist area, such as vascular services, would remain unaware of high-profile national guidance, such as that discussed above. However, many guidelines will also depend upon actions by non-specialists, such as timely referrals or appropriate investigations instigated in primary care or by other specialties. These may require specific measures disseminate guidance to other disciplines.

A second possibility is that recommendations may not be followed, despite a desire to do so, because the necessary resources are not available or accessible. This appears to be the case with some of the examples given above, although there may be different reasons and solutions. Although 'lack of resources' is often cited as a reason for the inability to provide a service, the underlying principle of making recommendations based upon a measure of cost effectiveness, compared to a threshold, is that more cost-effective activities will displace those that are less cost effective, thus improving overall value-for-money. However, there are several reasons why this may not occur. There may be resource limitations, such as difficulties recruiting staff with the appropriate skills or lack of capital equipment, less cost-effective treatments may be mandated for other reasons, or some activities may be seen as higher priority, despite lower cost effectiveness.

In the case of supervised exercise programmes for intermittent claudication, these remain unavailable in many places, despite a recommendation reflecting evidence that, in many cases, they would be a cost-effective alternative to more invasive and costly procedures. The difficulty in this case is that the provision of such facilities would require funding as a service development, whereas the savings from disinvestment in the services that would be replaced are from a separate budget and may be difficult or impossible to realise.

Another example of lack of access limiting ability to follow guidance is the variable access to recommended treatments for varicose veins. In this case the difficulty lies in conflicting guidance from various local commissioners that over-rules the national guidance. This may represent a conflict in values and objectives between the local and national policymakers, although local commissioners may also lack the ability to vire resources from less cost-effective services. It may be that there are local factors that make different guidance appropriate, but this may also reflect differing values in relation to competing criteria of cost effectiveness, urgency, severity, and perceived importance. Whatever, the underlying reasons, this creates a situation in which there is a lack of equity due to regional variation in access to services. [12] Furthermore, conflicting local and national guidance creates both inefficiency and confusion.

Another potential reason for failure of implementation is where those making decisions are aware of the guidance and have the recommended options available to them but choose an alternative course of action. This may be because they have different interpretations of the evidence, differing objectives, values or preferences, or a view that their specific circumstances warrant deviation from the guidance. This may be entirely appropriate in situations where the guidance is intended to inform clinical practice and is in keeping with the NICE advice about making decisions using NICE guidelines, which states "*We're working with other leading health organisations to encourage shared decision making between the people receiving and delivering care*".

However, there is a conflict when the objective of the guidance takes a societal perspective and aims to maximise the cost-effective use of resources or address health inequalities. To allow individuals to overrule such guidance both undermines their purpose and may also exacerbate any inequalities. Successful implementation of such guidance requires some levers to promote compliance. If the guidance relates to the provision of costly drugs or procedures, then this is likely to be through commissioning arrangements. This may be straightforward where there is a blanket recommendation against a particular technology. Where guidance is more nuanced, with specific clinical circumstances in which recommendations apply, then implementations through commissioning arrangements becomes more difficult. It is necessary for commissioners to collect and interpret sufficient clinical information to verify compliance, and this may not be routinely available.

The alternative is to promote adherence to guidance through measures that incentivise professionals and/or patients. In some healthcare systems, particularly insurance-based systems, 'value-based' patient co-payments may be used to encourage patients to adopt more cost-effective healthcare. Even in publicly funded healthcare systems, such as the NHS, top-up payments for treatments that would not generally be considered cost effective, has been accepted, despite the controversy that it caused. [63] Clinicians and managers may be incentivised by 'best practice tariffs', [64] or more direct rewards or penalties for non-compliance. However, as was seen with the experiment in GP fundholding in the 1990s, there is a danger that financial incentives that are aimed at influencing clinical practice may create tension between healthcare professional's roles as patient advocate and their competing financial responsibilities. [65] These tensions also risk undermining trust and the relationship between professionals and patients.

In the example of EVAR, both the technology appraisal and the subsequent guideline suggested that, in many situations, EVAR was not cost effective when compared to open surgical treatment. This was a consistent finding in the extensive economic analysis that was carried out for both sets of guidance. The guideline suggested that, for this reason, practice needed to be rebalanced towards open repair. However, there is no mention of cost effectiveness, or measures to drive such changes, in the recommendations or aids to decision making that are provided centrally by the NHS, individual commissioners or providers. [66]

Perverse incentives

The final area that may contribute to the failure of implementation of national guidance are the other drivers that may encourage non-compliance. Financial considerations may influence practice, either on the organisational or individual level. Reimbursement arrangements, and in the NHS, national tariffs, may affect treatment choices. Best practice tariffs aim to have a positive influence on practice, but other influences, such as unbundling of admissions for a course of management, treating bilateral conditions as separate procedures, variations in coding practice, or selecting to admit patients as an emergency may influence income and thus alter practice. Commissioning and funding arrangements may have a significant impact on practice. [67] On an individual basis, private practice and waiting list initiatives may alter clinician choices [68-70] and financial impacts of treatment falling of patients, such as travelling costs and loss of earning, may alter patient choices. [71]

Other potential sources of perverse incentives are academic and commercial considerations. Vascular services are mainly concentrated in larger teaching centres, where research funding and academic outputs may be highly valued, leading early adoption of new technologies and a desire to undertake research, much of which is commercially funded, thus leading to potential conflicts of interest. Many commercial studies may be 'seeding studies', having marketing rather than scientific objectives. [72] There may also be commercial pressures on clinicians and providers to adopt certain technologies, through expenses for opinion leaders to attend meetings and provision of reduced prices on research devices. [73]

Other potential perverse incentives may occur through the arrangements for monitoring of professional standards the collection of outcome data and setting of targets. These may be counter-productive in promoting defensive practice, altering referral patterns, or distorting priorities.

Conclusions

Many of the difficulties that lead to the failure of implementation of guidance stem from fundamental conflicts in objectives. This primarily relates to the differences between individual and collective perspectives and has implications for the target audience, nature of the guidance and methods of implementation. This is exemplified by the different types of guidance, relevant to vascular services, that have been produced by NICE.

Interventional procedures guidance is based upon safety and efficacy. Apart from the rare cases where there is a blanket recommendation against a technology, it gives no indication of the appropriateness of a procedure for an individual patient, but only whether it should be available in routine practice or require special arrangements for consent or use within research. Thus, the target audience for the guidance is professionals and service providers, and the potential routes for ensuring implementation are, for example, through providers' clinical governance arrangements and professional bodies.

In contrast, technology appraisals take a societal perspective and are clearly based primarily on cost effectiveness, with the potential for other societal values, such as equity, to be considered. The guidance may not recommend the most clinically effective management for individual cases, so effective implementation is largely through commissioning arrangements. In the case of blanket positive or negative recommendations this can be achieved through purchasing decisions. However, the situation is more complex where there are conditional recommendations, as the commissioners may not have information that allows them to establish whether the specified conditions are met. This may require additional data to be collected, either prospectively, though submitting details for prior approval, or retrospectively, through additional analysis of clinical data, to establish compliance. For this to be successful, the recommendation must include clearly defined conditions, based upon measurable

individual parameters that are, or could be collected. The lack of such criteria in the case of EVAR, described above, resulted in failure of implementation, with clinicians and patients being free to select treatment on the grounds of individual preferences, without considering cost.

Clinical guidelines, produced by NICE, include a combination of recommendations based upon both clinical effectiveness and cost effectiveness. The NICE advice on making decisions using their recommendations suggests that this is aimed at patients and healthcare professionals, as part of a shared decision-making process. It seems unrealistic to expect that patients, without direct financial responsibility, will place significant weight on economic considerations in their decisions. Although it might be possible to influence professional advice to take account of societal impacts, this would conflict with their professional responsibilities as a patient advocate, and potentially undermine the relationship of trust with their patients.

Thus, the nature of guidance, target audience and methods of implementation depend upon both the perspective (societal or individual) and the main objective (e.g. safety/efficacy, equity, cost effectiveness, or clinical effectiveness). Safety/efficacy objectives are likely to be mandatory, aimed at providers and professionals and implemented through clinical governance arrangements or professional accountability. Those with societal aims of balancing value for money with equity and other policy objectives are likely to be aimed at commissioning and purchasing arrangements and may, necessarily, need to limit patient and clinician choice. In contrast, guidelines that are intended to inform shared decision making, are targeted at professionals and patients and need to provide the more nuanced advice that can inform such decisions. For such decisions that take account of personal and local circumstances, patient values and preferences, simple recommendations to 'consider' or 'offer' a technology are of little assistance, whereas more detailed decision aids based upon the evidence review are likely to be more helpful.

Recommendations

The following are suggestions relating to the development, presentation, implementation, and monitoring of guidance, based upon the previous analysis with the rationale for each recommendation.

1. All guidance should be clear about the objective of the recommendations provided and the perspective from which they have been developed (societal or individual).

   Rationale: The objective and perspective have significant implications for the target audience, methods of implementation and for monitoring adherence.

2. Wherever possible, recommendations based upon different objectives or perspective should be documented separately or, as a minimum, clearly identified as such.

   Rationale: Lack of clarity regarding the basis of the recommendation is likely to lead to confusion or distrust and may prevent successful implementation.

3. Recommendations that are aimed at meeting societal objectives, such as equity and value-for-money, should be implemented through purchasing arrangements, professional standards, or regulatory mechanisms.

   Rationale: Allowing freedom of choice for individual patients or their healthcare professionals is unlikely to result in decisions based upon societal rather than individual objectives.

4. Healthcare professionals should not be placed in the position of enforcing recommendations that are based upon societal objectives, where these conflict with clinical effectiveness, patient choice, or individual preferences.

   Rationale: This risks creating a conflict of interest between the duty of a professional as patient advocate, recommending the best management in a specific situation, and their role in meeting wider societal objectives, and thus undermines their position as a trusted advisor.

5. Where recommendations aim to achieve equity, value for money or other societal objectives, but apply only to a subgroup of eligible patients, there needs to be a clearly identified and adequate mechanism for equitable implementation that includes:
   a. Measurable and enforceable criteria for eligibility
   b. Mechanisms for prior approval of eligible cases or retrospective data collection to enable commissioners, rather than individual clinicians, to take responsibility for ensuring compliance.
   c. The costs and resource implications of any additional data collection and analysis should be included in calculations of cost effectiveness and the decision-making process.

   Rationale: without a clear mechanism for identifying eligible patients and monitoring adherence it is likely that implementation will be inconsistent due to personal preferences.

6. Where additional data collection is required to monitor adherence to guidance, this should be fit for purpose, collecting the relevant data for all potentially eligible patients, including those who may be excluded from intervention.

   Rationale: Many current registries are not fit for this purpose, for example failing to collect sufficiently rich clinical data to evaluate indications for procedures. Many are procedure-based registries, which do not consider those who may have been eligible for treatment but have been inappropriately excluded, for example, due to failure of appropriate or timely referral or defensive practice.

7. Where guidance aims at supporting individuals in shared decision making, recommendations should explore factors that may be relevant to personalisation, such

as personal risk factors, individual preferences, and disaggregated outcomes, using risk models and decision aids, as appropriate.

Rationale: Blanket recommendations based upon average risks and benefits are likely to be of little value in informing shared decision making in complex situations.

8. Where service developments are recommended that require additional investment consideration should be given to mechanisms for funding this or diverting the resources through linked disinvestments, or the use of ring-fenced budgets.

   Rationale: In some cases, implementation of cost-effective service developments is limited by failure to identify sources of funding for the required resources.

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Appendix 1. National guidance related to vascular services.

Title	Year	Notes	Organisation	Clinical area	Link
A04. Vascular Disease - Service specification	2013	12 months review not carried out	NHS England	Service configuration	https://www.england.nhs.uk/wp-content/uploads/2017/06/specialised-vascular-services-service-specification-adults.pdf
Provision of services for patients with vascular disease	2021	4th edition - first 2012	VSGBI	Service configuration	https://www.vascularsociety.org.uk/_userfiles/pages/files/Resources/FINAL%20POVS.pdf
Abdominal Aortic Aneurysm: A service in need of surgery?	2005		NCEPOD	AAA	https://www.ncepod.org.uk/2005aaa.html
Clinical Commissioning Policy: Complex Endovascular Stent Grafts in Abdominal Aortic Aneurysm	2013	April 2014 review date but not done	NHS England	AAA	https://www.england.nhs.uk/wp-content/uploads/2013/04/a04-p-a.pdf
Abdominal aortic aneurysm: diagnosis and management (NG156)	2020		NICE	AAA	https://www.nice.org.uk/guidance/ng156
Endovascular stent–grafts for the treatment of abdominal aortic aneurysms (TA167)	2009	Superseded by NG156	NICE	AAA	http://www.jvsmedicscorner.com/Surgery_files/NICE%20Endovascular%20stent–grafts%20for%20the%20treatment%20of%20abdominal%20aortic%20aneurysms%202009.pdf
Stent-graft placement in abdominal aortic aneurysm (IPG163)	2006		NICE	AAA	https://www.nice.org.uk/guidance/ipg163
Delivering a National Quality Improvement Programme for Patients with Abdominal Aortic Aneurysms	2012	Updated from 2009 version (VSQIP)	VSGBI	AAA	https://www.vsqip.org.uk/content/uploads/2017/06/AAAQIP-Public-Report-_VSGBI-August-2012.pdf
Vascular Surgery: GIRFT Programme National Specialty Report	2018		GIRFT	All	https://gettingitrightfirsttime.co.uk/wp-content/uploads/2018/07/VascularSurgeryReportMar18-Q.pdf
Stroke and transient ischaemic attack in over 16s: diagnosis and initial management (NG128)	2019		NICE	Carotid	https://www.nice.org.uk/guidance/ng128
Carotid artery stent placement for symptomatic extracranial carotid stenosis (IPG389)	2011	Replaces IPG 191, 2006	NICE	Carotid	https://www.nice.org.uk/guidance/ipg389
Carotid artery stent placement for asymptomatic extracranial carotid stenosis (IPG388)	2011		NICE	Carotid	https://www.nice.org.uk/guidance/ipg388/chapter/1-Guidance
Lower Limb Amputation: Working Together	2014		NCEPOD	PAD	https://www.ncepod.org.uk/2014lla.html
Peripheral arterial disease: diagnosis and management (CG147)	2012	Update 2018, 2020	NICE	PAD	https://www.nice.org.uk/guidance/cg147

Percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease (IPG433)	2012		NICE	PAD	https://www.nice.org.uk/guidance/ipg433/chapter/1-Guidance
Cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate for the treatment of intermittent claudication in people with peripheral arterial disease (TA233)	2011		NICE	PAD	https://www.nice.org.uk/guidance/ta223
Percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices (IPG380)	2011		NICE	PAD	https://www.nice.org.uk/guidance/ipg380/chapter/1-Guidance
A Best Practice Clinical Care Pathway for Peripheral Arterial Disease	2022	Updated from 2019 version (VSQIP)	VSGBI	PAD	https://www.vsqip.org.uk/content/uploads/2022/05/PAD-QIF-2022-Update.pdf
Saving Limbs, Saving Lives: A Call to Action to Reduce Inequalities in Lower Limb Amputation Rates	2019		VVAPPG	PAD	https://static1.squarespace.com/static/5981cfcfe4fcb50783c82c8b/t/5db71337802a67007f9f1be0/1572279114966/Saving+Limbs%2C+QX2019+Saving+Lives-+A+Call+to+Action+to+Reduce+Inequalities+in+Lower+Limb+Amputation+Rates+web.pdf
Cyanoacrylate glue occlusion for varicose veins (IPG670)	2020		NICE	VV	https://www.nice.org.uk/guidance/ipg670/chapter/1-Recommendations
Endovenous mechanochemical ablation for varicose veins.(IPG557)	2016		NICE	VV	https://www.nice.org.uk/guidance/ipg557
Varicose veins in the legs (QS67)	2014		NICE	VV	https://www.nice.org.uk/guidance/qs67
Varicose veins: diagnosis and management (CG168)	2013		NICE	VV	https://www.nice.org.uk/guidance/cg168
Ultrasound-guided foam sclerotherapy for varicose veins (IPG440)	2013		NICE	VV	https://www.nice.org.uk/guidance/ipg440
Endovenous laser treatment of the long saphenous vein (IPG52)	2004		NICE	VV	https://www.nice.org.uk/guidance/ipg52
Transilluminated powered phlebectomy for varicose veins (IPG37)	2004		NICE	VV	https://www.nice.org.uk/guidance/ipg37
Radiofrequency ablation of varicose veins (IPG8)	2003		NICE	VV	https://www.nice.org.uk/guidance/ipg8