NHS
Commissioning Board

Clinical Commissioning Policy: Complex Endovascular Stent Grafts in Abdominal Aortic Aneurysm

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Clinical Commissioning Policy: Use of Complex Endovascular Stent Grafts in the Management of Abdominal Aortic Aneurysm

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Prepared by the NHS Commissioning Board Clinical Reference Group for

Vascular Services

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Policy statement

The NHS Commissioning Board (NHS CB) will commission complex endovascular stent grafts for abdominal aortic aneurysms (AAAs), in accordance with the criteria outlined in this document.

In creating this policy the NHS CB has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality statement

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

Plain language summary

Abnormally dilated arteries are known as aneurysms. Their walls are weaker than normal arteries and prone to rupture. Aneurysms can be treated by insertion of a tubular device known as a graft. This forms an internal channel through which blood can continue to flow along the length of the weakened part of the artery. This can be done as an open surgical procedure with the insertion of a fabric tube into the artery to carry the blood through the damaged area. Alternatively, a different type of graft known as an endovascular stent graft can be threaded into the damaged section through another blood vessel. This policy describes the different types of stent grafts that are in use; fenestrated and branched endovascular stent grafts.

The use of these grafts for repairing aneurysmal disease of the aorta is an area of developing practice in vascular surgery. In order to assure patient safety and make the best use of NHS resources, arterial centres fulfilling the specified criteria may use complex endovascular stent grafts routinely only in the categories of patients undergoing elective surgery specified in this policy.

Information on the outcome of treatments for these patients will be collected and considered when this policy is reviewed.

1. Introduction

The use of fenestrated and branched endovascular stent grafts for repairing aneurysmal disease of the aorta is an area of developing practice in vascular surgery. Research to date indicates that there may be a reduction in immediate post-operative mortality compared to open operation. However, these devices are newer, more expensive and less well researched than the stent grafts that are used in other parts of the aorta. The lack of information on cost effectiveness and longer term uncertainties lead the NHS CB to conclude that these devices are not ready to be commissioned as a routine part of care. Early results are promising and there is no evidence to suggest that the use of this intervention should be stopped. Therefore, this policy aims to:

- ensure that such patients are treated in units with appropriate skills and experience.
- gather data to identify the most appropriate and cost effective use of these devices.
- evaluate the use of these interventions in the care of patients more generally.

2. Definitions

Abnormally dilated arteries are known as aneurysms. Their walls are weaker than normal arteries and prone to rupture. If this affects the aorta (the major vessel taking blood from the heart to the rest of the body) rupture can be fatal.

Aneurysms can be treated by insertion of a tubular device known as a graft. This forms an internal channel through which blood can continue to flow along the length of the weakened part of the artery. There are two ways of doing this. The first involves open surgery with the insertion of a fabric tube into the artery to carry the blood through the damaged area. Alternatively, a different type of graft known as an endovascular stent graft can be threaded into the damaged section through another blood vessel. In the case of the aorta, the endovascular stent graft is threaded up through the femoral artery in the groin and, once in the weakened area of the aorta, it is expanded and fixed in place above and below the damaged area.

Aortic aneurysms can occur along the whole length of the artery. Very commonly they occur in the abdomen, below the level of the kidneys. This is known as an infra renal aortic aneurysm. Less commonly, the weakening of the wall can occur higher up in the abdomen, at or extending above the level of the kidneys. This is the part of the aorta from which the arteries to the intestines and the kidneys themselves arise (the coeliac, mesenteric and renal arteries respectively). Open surgery for these higher aneurysms has been available for some time but more recently devices for endovascular use have been developed. Repairing an area of the aorta from which other arteries arise requires modified stent grafts with openings that allow blood to continue to flow into these important organs and at the same time,

strengthen the damaged arterial wall. The openings are known as fenestrations if they simply allow blood to flow out through the wall of the graft into the arteries, or branches if they are small extensions that insert into the openings of the arteries supplying the organs.

Assessing suitability, planning, and placing complex endovascular stent grafts requires considerably higher levels of precision and skill than for standard stent grafts (i.e. those used below the level of the kidneys). There is much less margin for error. Following the operation, patients need more careful monitoring and have the potential to develop additional complications compared to those having standard infra renal endovascular repair. It is important that any complications are detected and treated as soon as they occur to prevent organ damage and so, to be sure of getting the best outcomes for patients, the staff monitoring patients during this time need to have experience of this specific post-operative care. Many complex stent grafts are made up of a number of component parts. Yearly follow up by experienced staff is required to ensure that the graft remains correctly positioned and functioning effectively.

3. Aim and objectives

This policy aims to:

- maximise patient safety by minimising the risks inherent in the current non-commissioned and expanding use of these interventions
- ensure the use of these devices follows the IDEAL recommendations for the evaluation of new surgical techniques[1]
- support the collection of data on outcome that will enable the evidence base to mature more rapidly
- help identify the appropriate place for these interventions within the care pathway when considered against cost effectiveness and affordability.

The objectives are to:

- offer treatment to a population of patients in whom this intervention is likely to be most clinically and cost effective given the current device costs and available clinical data
- state the requirements for units likely to produce optimal patient outcomes in the evaluative phase of this technology
- monitor and evaluate the use of these devices through a detailed audit programme utilising existing databases.

4. Criteria for commissioning

Overview

This policy covers the treatment of patients whose aneurysmal morphology is unsuitable for standard infra renal endovascular procedures and in whom the sealing zone of the stent graft lies below the diaphragm and/or requires a branched device for treatment of the visceral arteries.

In the main this will relate to the use of fenestrated and or branched endovascular stent grafts, whether custom made, off the shelf or modified at the time of operation, but also includes other innovative techniques such as the use of chimneys, snorkels, periscopes and sandwich techniques.

This policy does **not** apply to the use of endovascular stent grafts solely within the descending thoracic aorta.

During 2013/14 any complex stent grafts for the treatment of abdominal aortic aneurysm not specified here will be subject to the same criteria for use except by explicit agreement with commissioners. This policy position will be reviewed annually.

Patient selection

The cost effectiveness of these procedures is unknown at present and the high cost of the devices precludes their unlimited use. In addition, there are limited medium and no longer term data on the safety and durability.

These factors mean that in order to assure patient safety and make the best use of NHS resources, complex endovascular stent grafts may be used routinely only in the following categories of patients undergoing elective surgery:

- patients who are judged to have a medium or high risk of perioperative mortality from open repair (e.g. >5%). Providers and commissioners will agree the objective measures that will be used to support this risk assessment. The local outcomes from open repair will be part of this decision process

- patients who are at low risk of mortality from open repair but in whom there are additional clinical factors which indicate a high risk of morbidity. Examples might be patients with previous abdominal pathology which is likely to have resulted in the development of adhesions or other factors which would make operative dissection difficult or those predisposed to significant blood loss.

These interventions are **not** routinely available to patients with a life expectancy of less than two years as a result of comorbidities (serious conditions or diseases that are also present). In assessing such patients, consideration should be given to the likelihood of aneurysmal rupture compared to the likelihood of entering the terminal phase of other conditions in the same time period. Patients who are not medically fit for operation should be treated to maximise their fitness and reassessed for surgery

or conservative management.

The longer term durability of these devices is uncertain and because of this and the risks associated with radiation exposure during life time surveillance, complex stent grafts should **not** be used in the following categories of patients:

those with a life expectancy in excess of 10 yrs. Consequently, caution should be exercised in considering the use of complex stent grafts in patients in their 60s who have good fitness levels

those in whom the aetiology of the aneurysm is congenital, syndromic or associated with a connective tissue disorder

Complex endovascular stent grafts should not be used in the repair of ruptured aortic aneurysm outside a research setting or evaluative framework agreed with commissioners.

Where a patient does not meet the criteria set out in this policy, the NHS CB may consider funding treatment if it can be demonstrated that there are exceptional clinical circumstances, in line with NHS CB policy.

Providers of complex endovascular stent graft services

This section of the policy describes the characteristics of a provider unit that is able to supply an evaluative framework in which complex endografting can take place. Taken in conjunction, the combined effect of these criteria is to describe a provider unit which:

- is an established vascular network arterial centre and in addition, provides this specific aspect of vascular services to a population in excess of 2 million people
- has an aortic practice commensurate with a catchment population of 2 million for tertiary referral (typically >100 aortic procedures annually)
- has a defined team responsible for the care of patients with complex aortic disease
- hosts multidisciplinary teams (MDTs) to appropriately select, treat and care for patients, intervening rapidly to minimise complications and deliver the best outcome for patients
- demonstrably contributes high quality evaluative data in a timely manner
- utilises, trains and develops the skills of existing senior staff and trainees in all disciplines relevant to these procedures.

As with the vascular reviews currently taking place, the thresholds referred to in this policy should be considered as minima rather than as targets; attributes should be considered “in the round”. Commissioners will seek service configurations that exceed the thresholds. If there are a number of potential providers sharing a population catchment with case series at or around the threshold, commissioners will encourage collaboration to establish a higher volume site for service delivery during this evaluative phase. Since patient numbers will be relatively small per

institution, capacity should not prove a constraining factor in achieving this.

Whilst each policy criterion relates to an important assurance for care delivery, they should not be considered in isolation as series of 'all or nothing' standards. Rather, they should be viewed together as describing a high volume arterial centre with significant experience of the management of complex cases as evidenced, for example, by the management of tertiary referrals. Where an arterial centre does not meet a specific criterion, commissioners will consider whether a convergence plan to compliance is appropriate or whether it may, together with other factors, indicate that clinicians working in this unit should collaborate with those in other experienced units within the population footprint. Again, the whole picture of how the unit compares to the concept should be considered. The professional judgment of experienced and informed commissioners will be central to these decisions.

This is an emerging technology which remains to be fully evaluated and as such, it is not appropriate that it is offered from all arterial centres. Providers of complex stent technologies should:

- be the arterial centre of a vascular network fulfilling the NHS CB service specification for vascular services and the additional requirements of this policy
- have a projected activity for these specific interventions commensurate with an annual case load in excess of 24-30 cases to maintain high levels of expertise in all professionals involved in the care pathway. Incidence estimates suggest that the provider will, therefore, serve a population of around 2.4-3million people. Current data suggests that in England this is likely to result in more than 10 but less than 20 such providers in the short term
- have experience of the whole patient pathway from assessment through intervention and post-operative care, to long term surveillance. In the case of many surgical procedures it is agreed that the institutional learning curve is completed and best patient outcomes more likely after 20 cases have been undertaken. As a result, providers of complex endografts should be able to demonstrate an established case series in excess of 20 as a minimum, but preferably in excess of 40 cases. In this context, case series is regarded as an indicator of extensive, long term experience in the management and care of this patient group both during the initial planning and operative episode and the longer term surveillance and potential re-intervention phase of care. For this reason, case series will be expected to be acquired over a significant period of time and will be considered as the number of cases recorded by a unit as at November 2012. Commissioners who are asked to consider the development of services likely to be at, or only just exceed the minima described in this policy, will require persuasion that there are specific and demonstrable population requirements that would not be better served by larger scale service configurations. In these circumstances, commissioners may consider that less experienced centres should establish joint working relationships with more mature units. These relationships would be characterised by input to MDT assessment, planning and follow up as well as shared operating experience. Similarly, units having only recently reached the

case series thresholds stated in this policy are unlikely to have the necessary extensive long term experience.

- be capable of hosting colleagues from all disciplines with existing expertise so that present skill levels are maintained and extended. This will ensure the resilience of the service and in addition, act to ensure a rapid dissemination to more centres should the evaluation confirm that these interventions represent a good use of NHS resources
- be able to demonstrate evidence of outcomes for complex endografts with sufficient activity to allow meaningful analysis
- be able to identify a core team responsible for the treatment of patients with complex aortic disease.

Once suitable providers are identified, interventions using complex endovascular stent grafts will only be commissioned from nominated units that are able to demonstrate:

- compliance with the requirements of an arterial centre as described in the service specification
- compliance with the Medicines and Healthcare Products Regulatory Agency (MRHA) requirements for an endovascular service. In particular, the availability of hybrid endovascular theatre, or the firm plans for installation within a short timescale
- a team of named surgeons and interventional radiologists, some of whom may have substantive appointments in other vascular networks, who are able to provide a sustainable service and to whom all such cases should be referred
- regular MDT meetings for the consideration of cases. Clinical management decisions will be recorded as will the number of patients turned down for surgery
- that the team delivering the interventions includes a core of personnel in each discipline who have significant experience with the procedure at all stages within the pathway. Typically this will include:
    - vascular surgeons
    - cardiothoracic surgeons where appropriate
    - theatre and radiographic personnel with specific vascular experience
    - anaesthetists with vascular practice
    - vascular interventional radiologists
    - specialist nurses
    - vascular scientists
- these core personnel should be available for each case at the relevant part of

the pathway

- timely contribution of complete detailed clinical data and quality of life measures to the National Vascular Registry and any other information systems to allow evaluation in due course. Data contribution is mandatory for providers offering these interventions
- support for patients and their families in assessing risk and making decisions on their care. This will go beyond the provision of written information leaflets. In particular, it will address the uncertainties associated with the use of these interventions together with the nature and risks associated with long term follow-up. Information available to patients should make clear the likelihood and nature of complications and re-interventions both in the published literature and the institution in which the treatment will take place
- regular systematic reporting of patient evaluation of care
- explicit and agreed protocols with referring networks to ensure the identification and timely referral of suitable patients. Practice should follow the national agreements which will be developed for referral criteria and pre-operative assessment to ensure consistency of practice
- commitment to on-going training of colleagues in other arterial centres. This would be demonstrated by the presence of regular opportunities for network clinicians to participate in MDT discussions, planning and training in the deployment of complex stent grafts and follow up surveillance within a framework that fosters the acquisition and dissemination of the skills. In this way the system can be prepared for the roll out of the procedures to other arterial units as the place of these interventions in the care pathway becomes clear. The process should be formalised and not left to *ad hoc* arrangements. These arrangements may form the basis of a mentoring programme to support the implementation of the roll out programme. Over time, training schemes can be expanded to all disciplines within the team.

5. Patient pathway

People with abdominal aortic aneurysms present to vascular services through one of three routes:

i) as emergency attendance with ruptured aneurysm

ii) as an elective or urgent attendance with symptomatic aneurysm

iii) as an elective attendance following incidental discovery of an aortic aneurysm during examination for another reason or thorough a screening programme

People attending A&E departments as an emergency are transferred to the nearest arterial centre for treatment (see service specification for details).

Elective patients suitable for complex endovascular stent grafting may undergo

initial investigations and imaging in their local hospitals, if the relevant facilities and expertise exist. However, the MDT discussion of their case; the planning of their procedure; their pre-operative appointments, the procedure itself and subsequent post-operative care, will take place in a nominated unit with the relevant skills and experience in using these more complex devices. This may, or more frequently may not, be the arterial unit that is closest to the patient's home. Post-operative outpatient care and longer term surveillance may be undertaken in the patient's local hospital, if imaging and reporting expertise exist, with the subsequent MDT discussion involving the nominated centre. On-going clinical responsibility remains with the nominated centre and may be part of a shared care arrangement with the referring arterial network.

Providers of these services will collaborate with local vascular networks to ensure that potential patients are referred to the complex MDT within two weeks of the discussion within the local vascular MDT. Thereafter, a clinical management plan should be finalised within 60 days of presentation.

6. Governance arrangements

The governance arrangements will be those required of an arterial centre in the NHS CB service specification. Practice should follow the national agreements which will be developed for referral criteria and pre-operative assessment to ensure consistency of practice. Providers should adhere to the trust policies agreed with commissioners for the reporting of adverse and serious untoward incidents.

Providers will incorporate professional good practice as this becomes available in this sphere of practice.

7. Epidemiology and needs assessment

Incidence of patients with relevant pathology

The following estimates can only be considered indicative of likely activity for the following reasons:

- The current use of nomenclature in describing these aneurysms is not stable, the terms 'juxta renal' and 'supra renal' can be used to describe similar pathology. This will lead to coding inaccuracies.
- The interchangeable use of the terms 'juxta renal' and 'supra renal' in research papers make estimates of prevalence and incidence in the literature uncertain.
- Some complex stents are used to repair infra renal aneurysms when the landing zone of the upper margin of the graft lies in close proximity to this region of the aorta. These procedures may be coded as infra renal.

The estimates are derived from a number of sources and whilst each alone cannot

be considered robust, the estimates cluster around an estimate of 500 cases presenting annually. There are no data to indicate what proportion of those presenting will go on to have a procedure, although a recent period study of clinical practice in the UK may give indications shortly[2].

Summary of estimates of need

Source of estimate	Incidence (per million of general population)	Estimated annual number of cases presenting
Canadian surgeon opinion survey	10.18	532
Literature on prevalence of 15% of AAA		
Lower limit	10.44	545
Upper limit	12.35	645
UK Anecdotal prevalence of 10% of AAA		
Lower limit	6.73	352
Upper limit	7.97	416
Calculated from current UK observed use		457
Average of estimates		**491**

Details of Estimates

Estimate 1. A clinical and cost effectiveness analysis of the use of fenestrated endovascular aneurysm repair (FEVAR) in Ontario used an informal survey of observed incidence which estimated that a population of 11.4 million would generate 116 people presenting with juxta renal aneurysm annually[3]. Combining this incidence with population data for England[a] gives estimated annual numbers presenting as 531 based on the 2010 population estimate[b] and 575 based on the 2020 population estimate[c].

Estimate 2. A recent Vascular Society audit of outcomes from elective repair of infra renal AAA recorded 8380 infra renal repair undertaken in the UK over a two year period.[4]. It is not clear how assiduously juxta and suprarenal aneurysms were excluded from this analysis given the coding inaccuracies noted in the report. Estimates were performed with two assumptions, firstly that no supra renal aneurysms were included and secondly that all such aneurysms were included. This will generate a range in which the true estimate is likely to lie. 8380 AAA over two years represents an annual figure of 4190. The incidence of juxta renal

[a] ONS Mid 2010 population estimates for England http://www.ons.gov.uk/ons/rel/snpp/sub-national-population-projections/2010-based-projections/stb-2010-based-snpp.html#tab-Projections-for-regions

[b] Estimated population=52.2million (116/11.4)x52.2

[c] Estimated population=56.6million (116/11.4)x56.6

aneurysm within those presenting with AAA has been observed as 15.5% [5] and this figure of 15% is frequently quoted in the literature. This was then applied to the two assumptions.

Estimate 3. Clinical Reference Group (CRG) members' experience was that a prevalence of 15% was high compared to their practice and that the true figure lay nearer to 10%. The estimate was re-run with this figure.

Estimate 4. CRG members working in areas with a permissive commissioning policy supplied data on their recent activity together with the populations in their catchment area. The estimate was re-run with these data.

These estimates are not sufficiently robust to be considered accurate since they conflate prevalence and incidence data, together with observed cases going forward to procedure. However, they are adequate to give an indication of the order of magnitude of the likely need.

8. Evidence base

The literature in this area of vascular practice is sparse and often confined to case reports and small scale series. The most extensive literature relates to the use of fenestrated devices. A supporting literature review of fenestrated stent grafts was commissioned in 2012. [6]

Reports to date have focussed on the technical feasibility and clinical outcomes obtained in patients in whom endovascular repair is anatomically possible. Many studies report heterogenous patient characteristics usually combining those at a range of operative risk with those unfit for open operation. The majority of studies are case series. There are two systematic reviews of fenestrated grafts, however, their results are unreliable since they perform meta-analysis on heterogenous patient populations.

A recent UK registry analysis reported mortality related to complexity of the procedure and is probably the most reliable estimate of 30 day mortality at 4.1%[7] There appears to be a trend of increasing mortality as the number of vessels involved in the graft increases. Estimates of mortality from open repair vary with similar rates reported in highly selected cases. It is thought that in clinical practice however, mortality is in excess of 10% with many estimates being in excess of this figure, particularly for supra-renal aneurysms.

There are no randomised control trials comparing outcomes with open repair directly. Neither are there any other reliable data that compare mortality after fenestrated graft repair with open repair

There are no reported health economic analyses. The absence of assessments of quality of life or resource utilisation in reports (beyond length of stay and duration of procedure) means that there are no data on which to base estimates of cost effectiveness.

There are no data that relate patient outcome with unit throughput or experience.

There are no validated risk assessment tools that would enable robust prediction of post-operative mortality and upon which patient stratification by risk could be built.

Based on the available evidence, it would seem likely, but by no means proven, that in the short term at least and in skilled, experienced centres, the use of complex endovascular stents for juxta and pararenal aneurysm is at least as safe and effective as open repair. The paucity of mid and longer term data on durability and complications means that comparisons of outcomes can only be made in the immediate post-operative period and in the short term (i.e. up to 3 yrs).

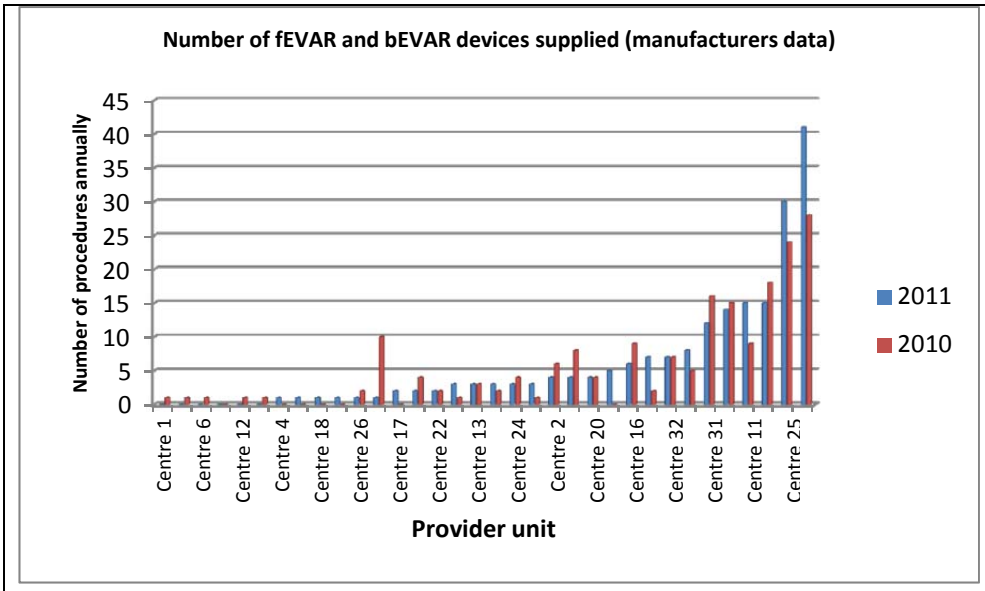
There are no safety concerns that indicate that this procedure should not be commissioned.

At present there are no direct data on which to make a judgement as to whether the additional costs associated with the use of fenestrated endovascular stents represents a good use of NHS resources.

All studies acknowledge the developing status of this procedure together with the limitations of the existing data and the importance of further study to better understand the current areas of uncertainty.

9. Rationale behind the policy statement

Nominated units Many vascular procedures demonstrate a clear volume outcome relationship. Whilst there are no data specific to complex stent grafts, the skills required for planning and deploying complex stent grafts are sufficiently different to those of standard infra renal repair, and the technology sufficiently new and costly, that it would be prudent to assume that the skills necessary to obtain good patient outcomes are not widespread. Analysis of supply data indicates that there is significant 'occasional practice' with units performing one or two procedures per year.



Learning from the introduction of standard infra renal endovascular repair and the managed introduction of novel devices in other clinical specialties, it is clear that this is unlikely to produce the best outcomes for patients. Concentrating activity in experienced units would be the most appropriate way forward and is the model used most often when new devices are introduced into clinical services.

There is a possibility that restricting these interventions to nominated units may lead to a deterioration of present skill levels amongst clinicians. This would be mitigated by requiring units offering complex endografting to provide training opportunities for those working in referring units, including all disciplines within the clinical team. In this way, once the cost effectiveness of the procedure has been identified and there is clarity on the place of these interventions in the care pathway, the roll out of the technology to all arterial units can proceed in a timely manner as appropriate.

Patient access criteria

This is an evolving area of practice and as such the long term outcomes are unknown. In contrast the safety and durability of the grafts used in open repair is well understood. At present the devices used are costly, in the region of £12,000-£30,000. In these circumstances it is important that available resources are targeted to those who are able to gain most benefit from their use and are not exposed to unknown risks.

Data submission

The developmental nature of complex endografting makes it essential that it is evaluated in clinical practice. Mandatory submission to registries and databases will ensure this.

Support for patient decision making

Endografting represents a significantly less invasive treatment option and it is clear that this will be attractive to many patients. The desirability of this must be weighed against the uncertainties that exist in the longer term and the requirement for long term follow up and possible re-intervention. These are difficult concepts and patients and their families are asked to make a judgement at a stressful time. It is reasonable to assume that they may need time to assimilate the information and weigh up the risks. Some may require the opportunity to speak to a member of the clinical team on more than one occasion.

Network training opportunities.

The purpose of this policy is not to establish an elite group of surgical units, rather it is to minimise the risks to patients that attend an unstructured wide-scale adoption of this technology. It is important that clinicians who work at other centres have the opportunity to work within the nominated unit to:

acquire the necessary skills prior to roll out to all units

be aware of the limitations of the procedure and hence be part of the decisions on an appropriate place in the management options

contribute to the data collection.

10. Mechanism for funding

Through the responsible Area Teams.

11. Audit requirements

Providers of these services will meet the audit requirements set out in the services specification and will report the additional information for this group of patients required by the relevant fields in the National Vascular Registry.

In addition, providers will make monthly submission to the commissioners which will demonstrate that appropriate patient selection.

12. Documents which have informed this policy

NHS CB Service Specification for Vascular services

Medicines and Healthcare products Regulatory Agency. Joint Working Group to produce guidance on delivering an Endovascular Aneurysm Repair (EVAR) Service (MHRA)
http://www.mhra.gov.uk/home/groups/clin/documents/news/con103000.pdf

13. Links to other policies

This policy follows the principles set out in the ethical framework that governing the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

14. Date of review

This policy will be reviewed in April 2014 unless data received indicates that the proposed review date should be brought forward or delayed.

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See Endnotes

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