NHS England

Guidance notes for commissioners implementing the policy on Complex endovascular stent grafts in the management of abdominal aortic aneurysm NHSCB/A04/P/a

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NHS England: Guidance notes for commissioners implementing the policy on complex endovascular stent grafts in the management of abdominal aortic aneurysm NHSCB/A04/P/a

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Prepared by the NHS England Clinical Reference Group for Vascular Services

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Executive summary

- With effect from 1st April, Area Teams should consider the appropriateness of current providers of complex aortic endografts for the repair of juxta and supra renal abdominal aortic aneurysm.
- Best patient outcomes are most likely to be delivered by arterial centres with significant experience of initial patient selection, peri operative management and long term surveillance.
- Area Teams should establish in the first instance whether one of the local arterial centres has a case series in excess of 40 cases accrued over a significant period of time and assessed at November 2012 as the data point. Where this is the case, care of these patients should take place in this provider.
- Where local providers have little experience of these procedures (see service specification and policy for details), Area Teams should discuss the arrangements necessary for onward referral of patients to the most appropriate experienced centre.
- In areas where there are a number of providers with case series at or around the minimum threshold of 20 cases, Area Teams should consider the requirements of the policy and begin discussion with providers to identify a single provider. In the interim, patients presenting to these units should be referred to the centre most closely meeting the criteria set out in the policy and service specification and hosting arrangements for referring clinicians established.
- Area Teams should ensure that their local vascular reviews incorporate the development of supra-network complex stent graft providers as part of the key work of establishing arterial centres. The requirements for MDT assessment of these less frequent, more complex cases together with the hosting arrangements for visiting clinicians, are similar to those required as part of arterial network development. The implementation plans of such centres should reflect this additional role.

1. Introduction

These guidance notes build upon the discussions that took place in the vascular Clinical Reference Group (CRG) during the policy development. They support the policy and suggest how Area Teams (ATs) might approach some of the local implementation issues identified through the development and consultation processes. The guidance should be read in conjunction with the policy, which gives the rationale for the criteria.

Whilst the guidance has the support of the vascular CRG, it remains an NHS England advisory document and as such, queries or requests for additional advice or support should be directed to the Accountable Commissioner for the Vascular Disease CRG or the local Programme of Care Manager for Internal Medicine in the first instance.

This guidance is provided at the outset of the implementation process and will be expanded as experience accrues. The aim is that Area Teams (ATs) are able to learn from each other as local solutions are found to the challenges of implementation. A number of foreseeable situations are dealt with in this guidance but it is recognised that other issues will arise. Where these are essentially clinical or professional in nature, ATs might consider contacting the Vascular Society of Great Britain and Ireland for advice http://www.vascularsociety.org.uk/

2. Summary of the policy and structure of the guidance

The aim of the policy is to offer treatment to a group of patients in whom these interventions are most likely to be cost effective and to assure patient safety by locating all stages of the pathway under the care of experienced clinicians. In common with other vascular procedures, investigations and follow-up can take place in the local network hospital, where facilities exist (imaging and/or reporting), however, the planning and deployment of these complex devices must only take place in arterial centres that can:

- accommodate multidisciplinary teams with significant experience of the care of this patient group at all points in the pathway.
- offer hosting arrangements to referring clinicians to participate in the care of their patients at all points of the care pathway

During policy development and in the subsequent consultation, it has become clear that there are two issues that are most likely to prove challenging in implementation. The first is the process by which arterial centres are selected as providers of complex stent interventions. The second concerns the importance of requiring a robust process by which selected providers host local clinicians both to maintain the skills of those with experience of these interventions and those yet to acquire the necessary skill level for independent practice. These areas receive the greatest attention in the following advice.

In addition, because the policy contains patient selection criteria; the monitoring that ATs will wish to put in place to confirm adherence to the policy is described in the section concerning audit.

3. Selecting provider units

The identification of arterial centers capable of becoming the providers of complex endografts services is inextricably linked to the wider vascular service review. In many areas, where service reconfiguration is complete or is well advanced, identifying units is likely to be relatively straightforward. In parts of England where the review has yet to complete, this policy may inform the location of arterial centres. However, in other areas where commissioners have supported the use of these devices in the past, the presence of a number of units with relatively low levels of experience may present a challenge to implementation if there is little consensus on the location of the arterial centre for the vascular network.

The last few years has seen an expansion of the use of complex aortic endografts with increasing numbers of units undertaking small numbers of procedures. Whilst experience in planning and deployment is developing in such units, it is clear that there will be less familiarity with medium and longer term surveillance and the management of late complications and appropriate re-intervention. It is in this latter area i.e. long term safety and durability, that there is greatest uncertainty about these devices. It follows then, that harnessing the skills of the most experience local clinicians is essential to optimal patient care.

4. Clinical experience

Best patient outcomes are most likely with careful patient selection (appropriateness rather than feasibility) by well established, experienced teams. Achieving this demands not only the technical skills associated with early part of the pathway but also the experience of relating patient characteristics and procedure to medium and longer term outcomes.

During 13/14, it is unlikely that institutions that have only recently reached the case series thresholds stated in the policy will have the necessary extensive experience of post-operative surveillance and management of patients over the medium and long term to be able to produce best patient outcomes or to deliver the highest quality of long term follow-up and re-interventions.

Activity analysis undertaken during November 2012 indicates that overall, there are already a sufficient number of geographically appropriately placed units capable of meeting the thresholds stated in the policy and assuring appropriate patient access. There is no population requirement to significantly expand the number of units offering a complex stent graft service during the evaluative period

Because of this, in assessing the case series of arterial centres wishing to offer highly specialised interventions such as complex endografting, a retrospective date should be used. In assessing case series and for the reasons given above, ATs should consider the series to be that number of complex cases recorded prior to November 2012

5. Case series and thresholds

Case series is used in this context as a proxy for the experience that a unit will have in patient selection, operative expertise and the short medium and longer term

management of patients in whom complex endografts have been implanted. During the evaluative phase of this technology, it is essential that service providers can demonstrate experience of monitoring patients closely and safely over a number of years. The ability to discern the need for watchful waiting or re-intervention is a key skill both for patient safety and for the judicious use of NHS resources. Not only is it important for the on-going welfare of individual patients but the experience of longer term outcomes also informs appropriate patient selection because knowledge of presenting clinical factors and subsequent outcomes are able to be related and brought to bear in future case selection.

Thresholds

There is no absolute research evidence to underpin the minimum threshold of 20 cases. However, in arriving at this value, the CRG took account of the 'learning curves' described for other surgical procedures both within vascular surgery and other surgical specialities. It is important to stress that this is an absolute minimum and unless there are unusual factors at play, ATs should look in the first instance to identify units where the case series exceeds 40. It is likely that suitable units will have accrued their case series over more than 5 yrs.

A retrospective cut-off date (November 2012) for case series assessment was chosen to prevent a 'race to the threshold'. Whilst it might be argued that the rapid acquisition of cases would serve to increase experience of the early part of the pathway, it fails to produce a team with the experience or skills necessary for effective long term management and involves less experienced teams delivering patient care. Equally, however, a unit that has a long established complex stent programme but has only performed a very small number of cases each year may lack the breadth of experience expected of a centre offering these specialist interventions. In considering this latter case, ATs should be aware of the past commissioning position. It is possible that, whilst the unit may have a small case series because of a local commissioning policy, the individuals in the clinical team may have high personal series having acted as proctors for other institutions. ATs should strive to retain the expertise that exists locally as the service structures change.

It is important to stress again that the case series accrued over a number of years is an indication of effective longer term management. During policy development the current spread of expertise was mapped using a combination of NHS and commercial data. Analysis revealed that there are likely to be providers who meet the higher threshold of 40 cases in most clinical senate areas and serving the Greater London population.

As a starting point, it is likely that in most areas there will be adequate service provision based on the position at November 2012, for the evaluation of this intervention. It follows then that, in most areas, it is unlikely that there will be a population need for expansion during this evaluative period. However, where there is no obvious candidate for the complex stent service provider, it is probable that one or more of the following situations exists:

- The local review of vascular services is not yet complete, arterial centres and their networks remain to be identified and agreed upon.

- There are a number of reconfigured arterial centres in the senate area all with cases series that are below the minimum.
- There are no units in the senate area that meet the thresholds because of a previous commissioning position on the use of these devices.

Prior to April 2013, there were a number areas of the country in which commissioners believed the technology was not yet mature enough for routine commissioning. In many cases local clinicians and providers have abided by these decisions. It is likely that many will feel aggrieved by the retrospective assessment point for case series. Viewed one way, the policy can be seen as a reward for 'bad behaviour' by units that continued to challenge what they would have considered restrictive commissioning decisions. This is an understandable opinion and commissioners should take particular care to ensure that the hosting arrangements for referring clinicians are robust, reliable and audited. Equally, in this context, it is important to reassure referring arterial networks that the presence of a complex endograft programme does not confer preferential status on that arterial centre nor its network and does not imply that future innovations in practice will automatically be located in those centres. The present situation has been inherited from local regional decision making and the single commissioning position of NHS England should mean that the introduction of new technologies is a more managed process in the future.

Where there is no obvious provider, the AT will have three options:

- Identify and contract with a local arterial centre with an established case series that meets the thresholds
- Develop an existing arterial centre to provide this service through a mentorship programme with an already experienced unit
- Consider that there is no need for a local service development immediately and contract with an experienced unit which may lie beyond the clinical senate area of the referring networks.

The flow diagram in figure 1 suggests some options for Area Teams in considering suitable service providers.

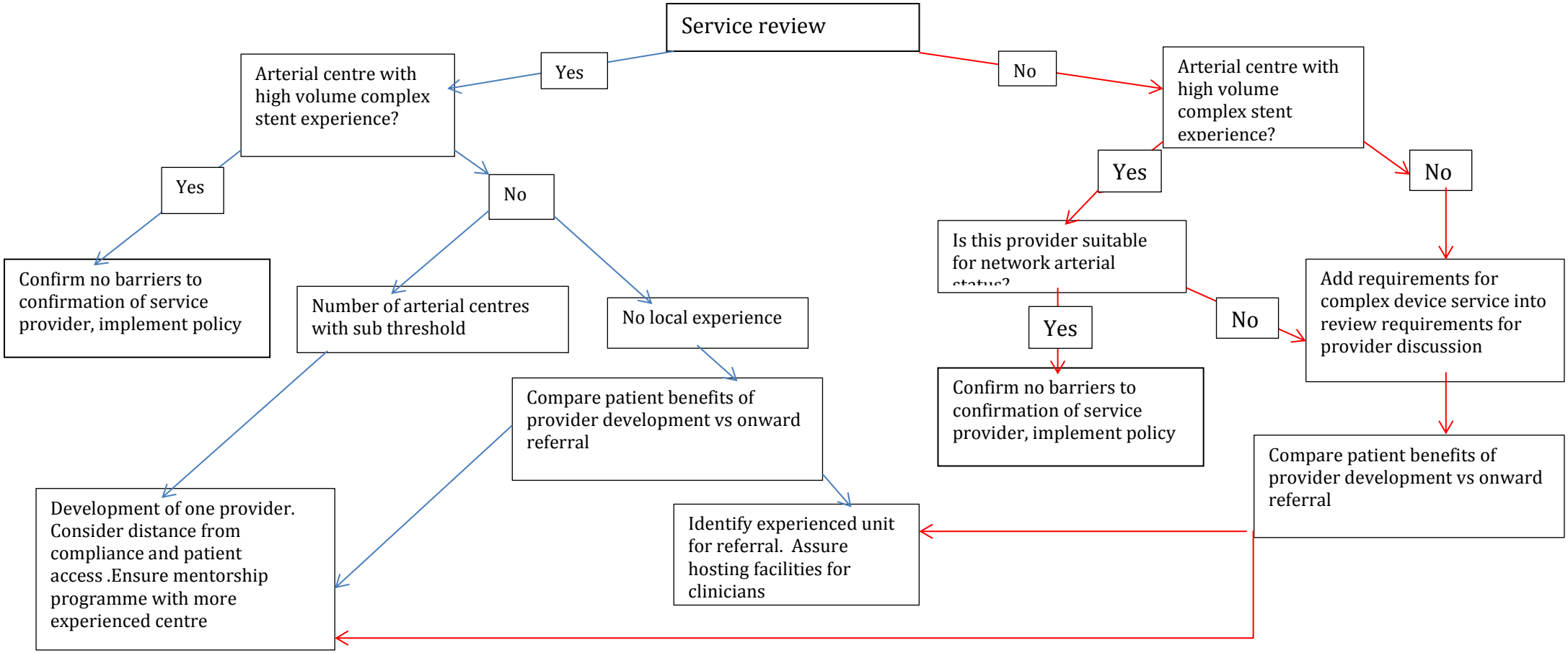

Figure 1 Flow chart depicting the influence of clinical experience on the commissioning options for a range of service configurations

6. Service reviews in progress

The absence of local agreement on the identity of arterial units will delay any local development of a complex endografting service. Since these procedures are elective, in the interim, patients should be referred to the nearest arterial centre with an established service.

Where there is no clear candidate for a complex endograft centre based on case series alone, ATs should consider whether there are compelling reasons to develop a local expertise and if there are, what other factors might indicate the best service for patients. These decisions will be similar to those relating to the identification of arterial centres in general. Amongst them would be the magnitude of the difference between existing facilities and those specified in the policy, together with geographic location and ease of access for patients from the referring networks. Local development of new services should only take place within a highly structured mentorship agreement with an established centre. The nature and intensity of this mentoring will naturally be determined by the experience of the clincians within the newly established or developing centre. However, it is likely that there will be planned, timetabled sessions at which experience can be gained in all parts of the care pathway with exposure to all patients treated by the experienced centre.

Equally, commissioners may judge that, since their local service review coincides with the evaluation period of this technology, priority should be given to establishing local vascular redesign. If this is the case, development of a complex endograft service could be deferred until the point at which the role of the intervention in routine management is more certain. In reaching this conclusion the AT should be assured that the existing referral pathways for complex endografts to experienced units outside the local arterial networks provides a satisfactory service for patients and that their populations are best served by delaying local development of complex devices until the wider service reviews conclude, the new configurations are established and the system is functioning effectively. As a principle, care should be delivered as close to the patient's home as is possible, so where facilities exist, the imaging required for diagnosis, planning and surveillance should be undertaken at the vascular facility closest to the patient's home. However, the interpretation of these images should be undertaken by clinicians who are part of the complex MDT in the experienced centre. The surveillance of existing patients will need to transfer in a similar manner. ATs choosing this route should be assured that the clinical referral arrangements are robust and that hosting arrangements are in place to enable referring clinicians to gain experience.

7. Mapping local expertise

ATs will want to understand the experience of their local providers. Unit records and HES data are the usual sources of this information. ATs may wish to compare the data they receive with that obtained by the NHS England as part of the policy development. Some of the data was provided in confidence for planning purposes and so cannot be widely circulated, however ATs may contact Accountable Commissioner for the Vascular Disease CRG or the local Programme of Care Manager for Internal Medicine and discuss how the data they have received from local sources compares with that held centrally by NHS England.

8. Other implementation issues

Merging clinicians with experience of different devices

The choice of device is a clinical decision and the members of the newly formed complex team should agree on which device will be used. That said, ATs should be assured that devices are deployed by clinical teams comprising individuals with experience in their use. Where clinicians cannot agree on the device(s) to be used, the experience of the hosting centre will be important and influential. ATs should take steps to ensure that patients receive competent clinical care as close to their homes as possible and are not asked to travel long distances for deployment of a specific device unless there is a sound clinical reason other than surgeon preference.

Hosting arrangements

The MDT required to consider complex endografts is similar in function to other vascular MDTs, however, because of the distances involved it is likely that there will be a need for virtual arrangements to prevent clinicians having to travel long distances and thus lose clinical time. The relatively low incidence of these presentations makes it likely that the additional meetings should not threaten capacity.

Implementation plan –

As with the plans for establishing the arterial centre and its network, commissioners should look to arterial centre providers to incorporate referral pathways and protocols to the complex endografts centres in their implementation plans. Similarly, in the case of the complex centre itself, in addition to the clinical pathways for patient care, the development of hosting and

if appropriate, mentorship arrangements should be present. These should be agreed with the AT

9. Quality and Activity monitoring

The policy details the specific outcome measures to be recorded and submitted to the National Vascular Database for quality monitoring.

It is expected that the activity levels for endovascular repair procedures will increase compared to past levels as patients who would formerly have had open procedures to repair their juxta or supra renal aneurysm receive endografts. However, annual activity should not be expected to exceed the total of all previous open and endovascular repairs listed for the operative codes L27.2 Endovascular insertion of stent graft for suprarenal aortic aneurysm and L28.2 Endovascular stenting for suprarenal abdominal aortic aneurism and within the usual service annual variation limits. In arriving at an appropriate comparator, ATs will need to take account of all referring networks who will supply activity to the complex centre. They will need to understand previous referral patterns to identify the increase in referral and look for the corresponding decrease in open repair within the referring networks compared to historical levels.