SAVING LIMBS, SAVING LIVES:

PATIENT ACCESS TO TECHNOLOGIES FOR THE DIAGNOSIS AND TREATMENT OF PERIPHERAL ARTERIAL DISEASE



ALL-PARTY PARLIAMENTARY GROUP **ON VASCULAR DISEASE**

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The All Party Parliamentary Group on Vascular Disease launched its inquiry on access to medical technologies for the diagnosis and treatment of Peripheral Arterial Disease on 20th June 2016. The Group's call for submitting evidence closed on 12th August 2016.

Alongside a call for written evidence, the Group held an oral evidence session in Parliament on 12th July 2016.

The Group would like to thank all those who participated throughout the course of the inquiry for their contributions.

The Group would also like to thank the following:

Industry:

Boston Scientific, Cook Medical, CR Bard, Medtronic

Others:

Martin Fox, Pennine Acute Hospitals Trust, Manchester Sara Petela, PB Political Consulting

FOREWORD

The All Party Parliamentary Group on Vascular Disease was established to raise awareness of vascular disease and to encourage actions to promote a greater priority for its prevention, early detection and best treatment. A particular focus of the Group over the course of 2016 has been looking at ways to reduce unnecessary lower limb amputations and associated early death related to Peripheral Arterial Disease (PAD).

A significant problem is the lack of awareness of PAD both by the public and doctors and of the potential benefits of prevention and treatment. This lack of awareness leads to delay in seeking advice, delay in diagnosis and delay in referral for treatment. The Group remains dedicated to increasing awareness of this condition and ensuring that patients have the best possible experience of vascular services.

Over 11,500 major lower limb amputations are carried out every year, the vast majority of which are as a direct result of PAD, diabetes or a combination of the two. I was shocked to see the latest statistics released by Diabetes UK, which 20 diabetes-related reveal that amputations are being performed in England every day. With the diabetes epidemic on the rise and set to continue, rates of amputation and other diabetesrelated complications will also increase, with a spiralling cost to the NHS. This trend must be reversed. Additionally, identifying non-diabetic patients with vascular disease must also be a focus for healthcare practitioners, and recognition must be given to the fact that this patient profile requires a distinct approach to be identified and treated in a timely manner.

Access to technology facilitates the earlier and more accurate identification of people at potential risk of amputation, heart attack, stroke and early death from arterial disease. The Group launched an inquiry into patient access to technology designed to help prevent lower limb amputation in summer 2016. The inquiry invited submissions and oral evidence

from experts involved with the diagnosis and delivery of vascular services. This report is the culmination of our findings and I encourage commissioners, NHS England and NICE in particular to adopt the recommendations, which have been developed to help drive service improvement as well as improve patient outcomes.

I remain highly troubled about the great deal of regional variation that exists in relation to access to technologies for the diagnosis and treatment of this condition. I hope that by understanding the barriers to access and through taking steps to overcome them, variable amputation rates and high rates of early death in people with PAD can be prevented.

Neil Camibad.

Neil Carmichael MP Chair of the All Party Parliamentary Group on Vascular Disease



SUMMARY OF RECOMMENDATIONS

All commissioners and providers should have a clear pathway in place for patients 1 suspected of increased risk of PAD and people with diabetes at risk of foot complications. ABPI testing should take place in a community or primary care setting wherever possible to 2 reduce the pressure on secondary care and to encourage early diagnosis and treatment. All patients should have access to a podiatrist - or another appropriately trained healthcare professional - in a community or primary care setting, to detect, test for and correctly refer 3 patients with CLI or PAD. CCGs should commission a Community Specialist Services and/or a High Risk Foot Team, which should include a vascular trained podiatrist. An appropriate number of clinical staff – including doctors, nurses and podiatrists 4 - should be trained to use diagnostic technologies to detect PAD and CLI. All CCGs should commission supervised exercise programmes for patients with 6 suspected and confirmed IC in order to prevent escalation of the condition. 7 A national awareness raising programme on PAD should be established. Every hospital must have access to a multidisciplinary foot care team. 8 This team must hold regular audit meetings to assess patient outcomes. NHS England must consider steps to become more flexible when commissioning or 9 supporting the commissioning of new technologies designed to improve patient outcomes. Drug eluting technologies are widely available and used within the NHS and NICE guidance 10 needs to be updated in order to reflect this reality in order to ensure that patients have access to the most appropriate technology no matter where they live in the country. Steps must be taken to eradicate the postcode lottery that currently exists in relation 11 to access to technologies designed to identify and treat PAD. The NHS and industry should work together to harness innovation and promote 12 better treatment for patients. The national tariff must support the appropriate and clinically-led decision to use a 13 particular type of technology for each individual patient. NHS England should consider how to introduce measures to incentivise the screening and 14 diagnosis of patients at risk of PAD in primary care settings, particularly if the QOF is to be removed.

ALL-PARTY PARLIAMENTARY GROUP **ON VASCULAR DISEASE**

1. PERIPHERAL ARTERIAL DISEASE (PAD), DIABETES AND LOWER LIMB AMPUTATION

- 1.1 PAD is caused primarily by progressive narrowing of one or more arteries in the lower extremities, resulting in decreased blood flow and oxygen to the affected tissues and muscles. The most common initial symptom of PAD is leg pain while walking, known as intermittent claudication (IC). Critical limb ischaemia (CLI) is a severe manifestation of PAD, and is characterised by severely diminished circulation, ischaemic pain, ulceration, tissue loss and/or gangrene.ⁱ
- 1.2 The NICE guideline group found that 20 per cent of people over 60 years of age have some degree of PAD.ⁱⁱ Risk factors for the disease include smoking, diabetes high blood pressure, raised cholesterol and age. In most people with IC the symptoms remain stable, but approximately 20 per cent will deteriorate and develop CLI.ⁱⁱⁱ PAD is often not diagnosed or proactively treated until it becomes severe and obvious (i.e. non-healing foot ulceration and/or severe claudication). This significantly increases the likelihood of a patient requiring a lower limb amputation.
- 1.3 PAD is a major contributor to healthcare costs because of the high rates of morbidity and impairment in quality of life which require treatment to reduce symptoms and prevent or treat ischemic events.^{iv} Ulceration and amputation reduce quality of life and are associated with high mortality, with a very significant number of patients dying just one year after major amputation.^v Studies show

that of CLI patients who require a below the knee amputation, 30 per cent will die within the first two years of amputation.^{vi}

- 1.4 While the risk of major amputation among patients with IC is low, the risk increases significantly in patients with CLI. Diabetes is a particularly important risk factor for development of CLI because it is frequently associated with severe PAD.vi+i Diabetes sufferers are 20 times more likely to have a lower limb amputation than people without diabetes due to PAD.vii Shocking statistics released by Diabetes UK have revealed that 20 diabetes-related amputations are being performed in England every day.viii The annual number of diabetes-related amputations in England is now 7,370 a year, compared to the previous figure of 7,042.viii This is particularly shocking given that it is estimated that up to 80 per cent of diabetesrelated amputations are preventable.ix
- 1.5 There are wide variations in amputation rates across the country and a contributing factor is likely to be differences in the organisation of care. The 2015 Atlas of Variation demonstrates that in some parts of the country you are nearly four times more at risk of lower limb amputation than in others.^{xi}
- 1.6 This report makes recommendations in relation to patients both with and without diabetes.



2. ACCESS TO DIAGNOSTIC TECHNOLOGIES

- Mild of Intermittent 2.1symptoms Claudication (IC) are typically managed in primary care, with several treatment options including advice to exercise, management of cardiovascular risk factors (for example, with aspirin or statins) and vasoactive drug treatment (for example, with naftidrofuryl oxalate).xii It should be stressed that all individuals with IC should have access to supervised exercise programmes, and that these programmes should always be promoted as an important method of preventing escalation of the condition.
- 2.2 Early diagnosis of arterial disease is crucial to prevent worsening of the condition resulting in CLI. A key component of ensuring effective and fast referral is ensuring that all commissioners and providers have a clear pathway in place for patients suspected of increased risk of PAD. This pathway must be made standard practice. There are, however, barriers to the early identification and diagnosis of this condition, some of which are directly linked to access to diagnostic treatments.

The ankle brachial pressure index (ABPI)

2.3 PAD is usually diagnosed by measuring the ankle brachial pressure index (ABPI). NICE stated in its 2012 guideline that ABPI is a key component of the lower limb vascular assessment for all people with suspected PAD.^{xiii} When appropriately used, ABPI measurement has the benefit of identifying patients with PAD so that effective treatment or referrals can be made to prevent an escalation in the condition. With this condition, fast and effective diagnosis is essential in order to prevent amputation. Non-diabetic patients with CLI often present with symptoms which, if identified and diagnosed correctly, can lead to swift intervention.

2.4 Identifying PAD and CLI in patients with diabetes can be more difficult as the symptoms are not always obvious or distinguishable. ABPI testing can help to detect this condition. ABPI testing should be readily available to all patients suspected of having PAD.

Training clinical staff

- 2.5 There is a general lack of awareness of PAD amongst physicians and patients. When patients present with limb pain, many doctors, podiatrists and nurses often suspect that the pain is of a musculoskeletal origin rather than PAD. This results in underdiagnosis and a subsequent under-treatment of the condition. Sometimes the result of this can unfortunately be amputation. A greater focus must be on educating clinicians who are likely to come into contact with this patient population.
- 2.6 It is not just a case of the symptoms of PAD being under-recognised which acts as a barrier to effective treatment. This inquiry has identified that there is a lack of trained clinical staff who are able to carry out the ABPI test. Many services do not carry out general training in this area, nor do they employ a clinical expert with the appropriate

understanding and experience of ABPI measurement. Untrained staff often feel uncomfortable interpreting the results and therefore are less likely to carry out the test to begin with. This results in the over-referral of people with various lower limb symptoms to Vascular Teams and conversely the underreferral of people with mild or early PAD or those with typical leg and foot symptoms. It is important that ABPI measurements are carried out by a trained healthcare professional who understands the implications of the measurement. Regular quality assurance checks should also be undertaken to ensure standards are maintained.

Diagnosis in community and primary care settings

- 2.7 Early diagnosis of PAD is crucial for effective treatment and therefore it is clear that a focus on diagnosis in primary and community care is required to prevent escalation of this condition. Having said this, in the majority of NHS organisations, there are largely no commissioned services that take on the responsibility of initial PAD assessment and treatment outside of hospitals. This lack of accountability by an individual or service can mean that there is a lack of incentive to drive forward improvements within vascular services, which ultimately impacts negatively on the patient.
- 2.8 Community Specialist Services, such as podiatry and High Risk Foot Teams, already have the staff with the requisite clinical skills, but have not been specifically commissioned developed provide NICE or to recommended limb vascular lower assessment and clinical treatment of PAD in most NHS organisations. Podiatrists are an under-utilised resource in this area. Often the focus on primary and community care

places an emphasis on GPs and nurses. Whilst it is crucial these groups are educated and trained in this area, it should be considered how podiatrists can be better utilised to more immediately meet patient need and reduce costs to the NHS.

2.9 Where commissioned specialist podiatry-led PAD services have been developed and are in place, these services have shown themselves to be implementing NICE Guideline CG 147, whilst being reasonably cost neutral.xiv Overall savings in NHS resources have been made through these interventions. These savings are made by achieving 75 per cent or more reductions in unnecessary suspected PAD referrals to Acute Vascular Units. This trend has been shown in each of the commissioned podiatry-led PAD services. These community-based services, staffed by skilled, experienced lower limb clinicians, ensure that PAD and CLI are diagnosed early in the disease progression. NICE recommended interventions have been widely implemented in partnership with GPs and existing Acute Vascular Teams to treat PAD. CLI patients have been fast tracked to Acute Vascular Teams as urgent/priority referrals by confident, expert diagnosing clinicians. This is a cost effective and wholly positive scenario, but has only so far been implemented in fewer than 10 Clinical Commissioning Groups (CCGs) nationwide.

Alternatives to ABPI

2.10 In patients with PAD other imaging technologies are often indicated to aid treatment, such as Doppler monitoring, duplex ultrasound, MRI and CT angiography. This inquiry has found that recruiting the adequate number of appropriate clinicians – for example sonographers to carry out imaging – continues to be a challenge. Another challenge is that the service is often not available out of hours and at weekends for emergency cases.

- 2.11 After diagnosis and referral, patients must have access to appropriate imaging. Specialised imaging - such as Duplex ultrasound, MRI and CT - is usually carried out prior to interventional treatment. It is important that patients have access to imaging technology when this is required.
- 2.12 Vascular Services across the majority of England are provided by specialist vascular centres. These centres have clear criteria they have to meet in order to be commissioned. There are a number of smaller hospitals that do not have vascular services on site; instead they refer to the local vascular centre. The Group supports the effective structuring of vascular services, but would like to reiterate the importance of equitable patient access to services and the technologies held within these services. Regional variation in patient access and quality of service is unacceptable which must be acknowledged and addressed by NHS England.
- 2.13 Patients have a right to the latest diagnostic technologies for the detection of PAD. Investing in diagnostic technology should lead to an increase in early diagnosis of symptoms of PAD and prevent the escalation of this condition. This early identification and treatment has long-term cost benefits to NHS services and therefore it is crucial that the NHS is not shortsighted when making investment and commissioning decisions.

- 2.14 In order to raise the profile of this condition more widely - amongst patients and clinicians - a national awareness raising programme for PAD should be established. This would require the involvement and support of the Government and healthcare to increase structures the public understanding of the symptoms of this condition. It should be noted that an increase in public awareness is likely to lead to an increase in the number of presentations of patients suspecting this condition in primary care. The inquiry has demonstrated that the primary care workforce, therefore, must be educated to effectively identify symptoms, carry out diagnostic tests and refer correctly.
- 2.15 The Group emphasises the need to ensure that steps are taken to ensure that all patients have access to, and are supported to remain within, supervised exercise programmes as well as other forms of initiatives that aim to modify risk factors, such as smoking cessation programmes. Supervised exercise programmes and smoking cessation programmes are recommended as first-line therapies for the treatment of claudication in patients with PAD, so awareness raising should include a focus on access to these programmes. Individuals should be educated on the importance of compliance with these programmes and the potential consequences of non-compliance. The inquiry found that there is an issue with huge variation in access to exercise programmes across the country, which must be addressed.



Recommendations

All commissioners and providers should have a clear pathway in place for patients suspected of increased risk of PAD and people with diabetes at risk of foot complications.

ABPI testing should take place in a community or primary care setting wherever possible to reduce the pressure on secondary care and to encourage early diagnosis and treatment.

Drug eluting technologies are widely available and used within the NHS and NICE guidance needs to be updated in order to reflect this reality in order to ensure that patients have access to the most appropriate technology no matter where they live in the country.

An appropriate number of clinical staff – including doctors, nurses and podiatrists – should be trained to use the latest diagnostic technologies to detect PAD and CLI.

All CCGs should commission supervised exercise programmes for patients with suspected and confirmed IC in order to prevent escalation of the condition.

A national awareness raising programme on PAD should be established.

3. ACCESS TO TECHNOLOGIES TO TREAT PATIENTS

- 3.1 First line management for patients with intermittent claudication (IC) should be engagement in supervised exercise programmes. In many cases, where patients are compliant with these programmes, the condition improves and intervention is unnecessary. The benefits of this approach extend beyond the patient, with a clear costbenefit to the NHS. This approach, therefore, should be encouraged and efforts made to educate patients about the importance of participation and compliance in these programmes.
- 3.2 This report does not intend to set out when intervention is appropriate, but focuses on access to technologies once intervention has been ascertained as the appropriate option for a patient. For many patients whose condition requires intervention, the most effective way of avoiding PAD-related amputations is to restore blood flow through revascularisation. It should be noted that a revascularisation strategy is individual to the patient, and there is no one-size-fits all solution. However, when revascularisation is determined to be required, it must be carried out in a timely fashion and certainly before any deterioration in the patient's condition has occurred.

Implementing and utilising effective pathways

3.3 69 per cent of respondents to the Group's inquiry do not believe that every patient who requires intervention is assessed

appropriate foot/vascular by an multidisciplinary team who can then refer on correctly. Multidisciplinary foot teams are acknowledged by NICE as crucial to the successful and high quality delivery of foot services for people with diabetes, in particular rapid referral^{xv}. Every acute hospital should have a multidisciplinary foot care team to determine the best strategy for a diabetic patient. Currently almost one third (31 per cent) of hospitals are without such a team and only 58 per cent of inpatients with new or deteriorating foot disease are seen within 24 hours of referral.xvi Where multidisciplinary teams are in place, it is important that robust meetings take place to ensure that patients are managed effectively and appropriately treated. Nondiabetic patients must also have swift access to appropriate healthcare professionals in order to achieve timely diagnosis and treatment.

3.4 The Group would like to encourage continued and enhanced collaboration between Vascular Surgeons, Interventional Radiologists (IRs) and other members of Multi-disciplinary teams (MDTs). Commissioning guidelines for vascular services state that any patient in whom intervention planned, including is amputation, must be discussed within an MDT meeting composed of radiologists, surgeons, nurse practitioners, podiatrists and other appropriate members of the team. Commissioners should ensure that MDTs appropriately staffed and that are commissioning guidance is followed in order to deliver excellent patient care and improved outcomes.

Adopting technological innovations

- 3.5 Surgical bypass has been the main stay of treatment to improve the circulation (revascularisation) of patients with PAD. However, this is a major operation for a patient and the introduction of less invasive revascularisation methods such as angioplasty and angioplasty combined with stenting has been encouraging as it offers less invasive treatments for patients with PAD.
- Current NICE 3.6 guidelines on revascularisation for Lower Limb Peripheral Arterial Disease (CG147) recommend offering percutaneous transluminal balloon angioplasty (PTA) after advice on risk factor modification has been reinforced, supervised exercise programme has been attempted and imaging has confirmed a lesion suitable for intervention. Stenting is currently not recommended as a primary treatment for femoropopliteal disease (linked to calf claudication). If stenting is needed or offered, the NICE guidance currently specifies that bare metal stents should be used.^{xvii} Despite these clear guidelines, there is profound variation in revascularisation rates within England and many patients suffer amputation of their leg without being offered revascularisation, which adds weight to the argument that outcomes for patients with vascular disease are dependent on an individual's postcode. No patient with PAD should undergo amputation without offered revascularisation and being patients must be referred in a time to allow this.
- 3.7 There are multiple technologies in revascularisation which have been shown to have various degrees of effectiveness. Drug eluting technology is one of the most recent

technological innovations being used within the NHS and private practice. The use of drugs incorporated into stents or angioplasty balloons offers the possibility of improving long-term outcomes. Several new technologies have been developed such as bare nitinol stents, drug-eluting stents, covered stents, and drug-coated balloons to improve long-term outcomes after angioplasty of the femoral and popliteal arteries.^{xvii xix} A number of randomised controlled trials (RCTs) have shown the superiority of some of these technologies over plain balloon angioplasty.xx Different devices have also been developed with an aim to further improve primary efficacy and restenosis rates, for example atherectomy, cutting balloons, brachytherapy and cryoplasty. xxi xxii xxiii xxiv

- When NICE produced its guideline on the 3.8 diagnosis and management of PAD in 2012, it did not include a recommendation for the use of drug eluting technologies of any type. It was determined that there was a lack of robust data to support its use at this time. However, efforts are being made to collect data to support the use of drug eluting technology in critical limb ischaemia and in reducing amputation rates - there are currently two large national studies (BASIL 2 and BASIL 3) being funded by the National Institute of Health Research (NIHR) aimed at determining the best treatment for individual patients.
- 3.9 In February 2014, NIHR published its Health Technology Assessment which concluded that the evidence showed a significant benefit to reducing restenosis rates for drug eluting technologies, which were also found to be cost effective within NHS thresholds when compared to standard care.xxvi Furthermore, economic analysis of endovascular drug eluting treatments for femoropopliteal artery disease in the UK has

shown that widespread adoption of drug eluting technologies for femoropopliteal disease would add meaningful clinical benefit (Target lesion revascularisation (TLR) rate reduction) at minimal additional costs to the NHS over a 2 year time horizon.

- 3.10 Just 25 per cent of respondents to the Group's inquiry felt that all patients who could benefit from drug eluting technologies have access to it. Within some CCGs this technology is used routinely, whilst in other areas it is not available. The Group is concerned that access to this technology varies across the country, which leads to a postcode lottery for patients. The Group believes that patients should have equal access to medical technologies designed to treat PAD, if clinically appropriate, wherever they live in the UK and that NICE guidelines should reflect current practice.
- 3.11 The inquiry responses reveal a significant level of frustration from a variety of

respondents who perceive the need for technological innovation to be at odds with the speed at which randomised controlled data and a technological evidence base are able to be established, which is required for NHS England to make a commissioning decision. With technologies advancing at a fast pace, there is a risk of the NHS constantly playing catch up, and patient access to the most appropriate treatments suffering as a result of this.

3.12 The All Party Parliamentary Group believes that NHS England must consider steps to become more flexible when commissioning or supporting the commissioning of new technologies designed to improve patient outcomes. Drug eluting technologies are widely available and used within the NHS and NICE guidance needs to be updated in order to reflect this reality and ensure that patients have access to the most appropriate technology no matter where they live in the country.

Recommendations

Every hospital must have access to a multidisciplinary foot care team. This team must hold regular audit meetings to assess patient outcomes.

NHS England must consider steps to become more flexible when commissioning or supporting the commissioning of new technologies designed to improve patient outcomes.

All patients with PAD should have equal access to the appropriate treatments as recommended by NICE. NICE should recommend the use of drug eluting technologies (when clinically appropriate) in its updated 'Peripheral Arterial Disease: Diagnosis and Management' guideline.

Steps must be taken to eradicate the postcode lottery that currently exists in relation to access to technologies designed to identify and treat PAD.

The NHS and industry should work together to harness innovation and promote better treatment for patients.

Tariff and reimbursement

- 4.1 One of the issues that came through strongly during the course of the inquiry was that the current reimbursement to providers for the treatment of patients with PAD rarely cover the true health care costs. Patients with PAD often need complex treatments, rehabilitation and support to return to their home environment. The current tariffs do not cover these costs and patients may be denied appropriate treatments or suitable rehabilitation as a result. The tariff should support the appropriate and clinically-led decision for revascularisation methods to be performed, or amputation in the cases where amputation is the most appropriate course of action, as deemed appropriate for each individual patient.
- 4.2 The Best Practice Tariff (BPT) for angioplasty and stenting procedures was introduced in 2012/13 and specified that Trusts would receive a financial incentive for every patient they treated. This does not seem to have impacted the number of patients receiving stenting and angioplasty procedures, therefore questioning the success of the BPT in extending patient access to interventional radiology procedures and technologies. NHS England should consider how this might be addressed, particularly within the context of the recent removal of the interventional radiology best practice tariff.
- 4.3 It must also be considered that often patients with PAD have other co-morbidities, which means that such patients will have many touch-points across the healthcare system. Integrated incentives should therefore be

introduced to ensure that all touch-points benefit from best practice across the care continuum of this patient cohort.

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4.4 Questions around reimbursement and incentivisation are further compounded by financial systems that fail to discriminate between more specialist treatments that have better outcomes for limb salvage. The current HRG system does not provide adequate granularity to differentiate between more or fewer specialist services. This results in a situation in which high quality specialist services are often loss-making when competing with the alternative, less specialist services that contribute to the pricing structure. This provides а further disincentive to appropriate reconfiguration. NHS England should consider how to develop a financial arrangement that adequately incentivises high quality specialist treatment and adequately funds the provision of services with 24/7 availability of specialist surgeons and radiologists. This may require some modification to tariff prices and categories to differentiate between such treatments, or a recognition of separate weighting for specialist services that have been shown to meet a set of defined criteria.

Incentivising primary care

4.5 As has been previously referenced, the inquiry has identified that a key way of achieving improved early diagnosis rates for PAD is to shift the focus to primary and community care for diagnosis. NHS England should consider how to introduce measures to incentivise the screening and diagnosis of patients at risk of PAD in primary care settings, particularly if the QOF is to be removed. Through encouraging primary care clinicians to take proactive steps to diagnose this condition, the Group believes that this would reduce the number of patients whose condition deteriorates and therefore need to be treated in secondary care.

Recommendations

The national tariff must support the appropriate and clinically-led decision to use a particular type of technology for each individual patient.

NHS England should consider how to introduce measures to incentivise the screening and diagnosis of patients at risk of PAD in primary care settings, particularly if the QOF is to be removed.

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