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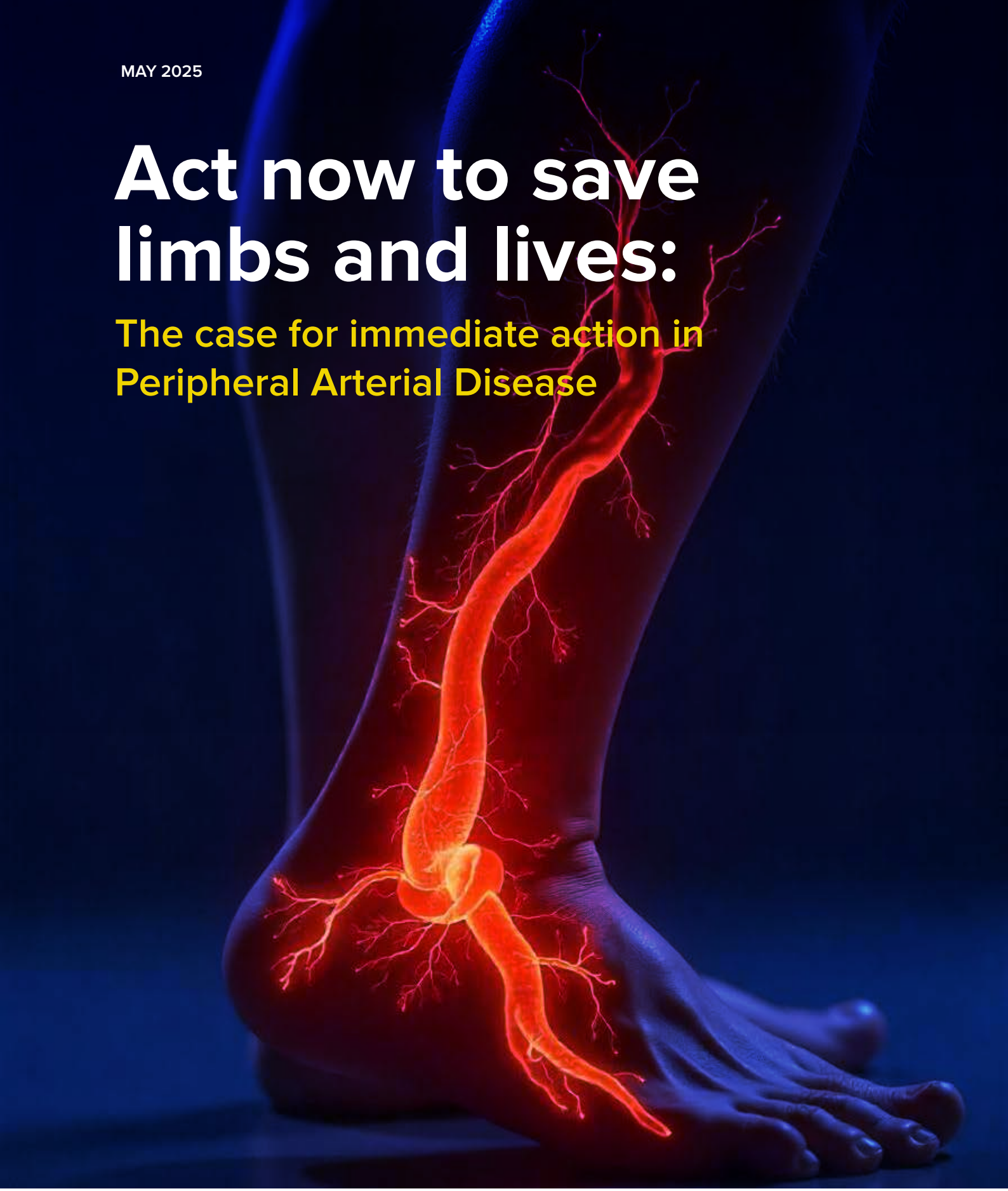
Act now to save limbs and lives:

The case for immediate action in Peripheral Arterial Disease



LEGS MATTER!

CIRCULATION FOUNDATION
The Vascular Research Charity

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Executive summary

Heart and circulatory (cardiovascular) diseases affect 7.6 million people in the UK, and the British Heart Foundation (BHF)[1] estimates that more than half of us will get a heart or circulatory condition in our lifetime. In his recent report into the state of the NHS, Lord Darzi[2] noted that care for cardiovascular conditions is going in the wrong direction, with standards of care varying dramatically across the country. Nowhere is this more true than in the diagnosis and treatment of Peripheral Arterial Disease (PAD).

Many patients with PAD in England face significant challenges: diagnosis can be slow and treatment options vary significantly across the country. PAD can be a debilitating condition and is one of the biggest causes of lower-limb amputations in the UK, with amputations reserved as a last resort treatment option when the disease is too severe and alternative options are not available or have failed.

Every PAD patient in the UK should have access to early diagnosis and effective treatment that delivers long-term, positive outcomes, but this is not a reality. In line with Lord Darzi's recommendations, the Government wants to move care closer to home and encourage greater collaboration between different services. Darzi also recommended the Government address the low rates of technology uptake across the health service. Reforming clinical pathways for PAD and improving access to innovative treatment options can help the Government achieve these shifts, but this will require collaboration with healthcare professionals from across the system, medical technology manufacturers, charities and patient groups. This report has been produced following a timely roundtable event held in the Houses of Parliament. It discusses the following:

Overview of PAD

PAD is a form of cardiovascular disease characterised by the narrowing of arteries, reducing blood flow to the limbs, primarily the legs. It shares risk factors with other cardiovascular diseases, including smoking, diabetes, hypertension, high cholesterol, and obesity. Collaborators noted that in advanced cases, patients have a 60% risk of death at 5 years, worse than many end-stage cancers.

[1] https://www.bhf.org.uk/-/media/files/for-professionals/research/heart-statistics/bhf-cvd-statistics-uk-factsheet.pdf
[2] https://assets.publishing.service.gov.uk/media/66f42ae630536cb92748271f/Lord-Darzi-Independent-Investigation-of-the-National-Health-Service-in-England-Updated-25-September.pdf

The current challenges in PAD diagnosis and treatment

Although PAD is a common condition, affecting 20% of people over 60 in the UK, the general population and clinical peers in both primary and secondary care have limited awareness and understanding of PAD. This is in contrast to other cardiovascular diseases, such as strokes. Collaborators also discussed challenges such as limited NHS resources, inequality in treatment access and lack of community-based care.

The case for greater Government recognition and investment

Collaborators discussed the numerous benefits of further investment in and greater recognition of PAD. These include improved patient outcomes, cost savings across the health service, public health benefits and greater economic activity. These benefits chime with many of the Government's priorities.

Recommendations for greater Government and NHS investment

Collaborators discussed specific policy recommendations for the Government and NHS stakeholders. These policy recommendations range from short-term interventions to longer-term changes. Collaborators agreed that there was an urgent need for a public awareness campaign, which would help inform patients of potential symptoms and encourage them to seek treatment or advice from GPs at an early stage. Other policy recommendations include implementing more efficient clinical pathways and improving access and funding routes for the adoption of innovative technologies.

Introduction to roundtable

A roundtable was held in the Houses of Parliament on 3rd December 2024 that brought together key stakeholders from across the vascular ecosystem, including clinicians, patient representatives, patient groups, and parliamentarians. It was hosted by Jim Shannon MP, Chair of the Vascular and Venous Disease All-Party Parliamentary Group, and chaired by former NHS Regional Director for London, Dr Anne Rainsberry. The roundtable took place due to concerns about the challenges and disparities in treatment of PAD, and the lack of awareness of the disease among the public and healthcare professionals which has had dramatic and unfortunate consequences - with large numbers of people in England having life-changing and unnecessary lower-limb amputations.

The objective of the roundtable was to discuss these challenges, identify collaborative solutions to improve the patient pathway, drive awareness of PAD among clinicians and patients, and brainstorm ways to ensure timely access to innovative treatments to prevent disease progression and avoid limb amputations where possible. It emphasised the need to address the growing burden of PAD and highlighted the importance of collaboration between healthcare professionals, policymakers, and patient groups to drive change.

This report will summarise the roundtable discussion, and present a number of recommendations to drive awareness and service improvement of PAD among the public, the NHS, and the Government.

Overview of Peripheral Arterial Disease

- PAD is a chronic condition characterised by the narrowing of arteries, reducing blood flow to the limbs, primarily the legs. It is caused by a build-up of plaque, made up of calcium, fatty material, cholesterol, and other substances that can build up with the walls and lumen the peripheral arteries.

- PAD is a common condition affecting an estimated 200 million people globally, with a prevalence of one in five[3] people over 60 in the UK. It has a disproportionately high rate among the elderly and people in lower socio-economic backgrounds.

- PAD shares risk factors with other cardiovascular diseases, including smoking, patients with diabetes, hypertension, high cholesterol, and obesity. Smokers have up to a four-fold[4] increased risk of developing PAD compared to non-smokers and are twice as likely to need limb amputation, and diabetics who smoke have an eighty-fold risk of major amputation.

- PAD can manifest as leg pain, cramping, numbness, and non-healing wounds. In severe cases, it can lead to chronic limb-threatening ischaemia (CLTI), tissue necrosis, and amputation, with around

a third of people needing a lower limb amputation within a year of diagnosis without undergoing a revascularisation procedure. The impact of amputations are severe and lead to lifelong complications, 23.7% of people with lower limb amputations are likely to die within 1 year following the procedure.[5]

Severe PAD poses a significant burden on healthcare systems and individuals, leading to reduced quality of life, amputations, and increased mortality rates. Patients with PAD with rest pain and tissue loss (CLTI) have a 60% risk[6] of death at 5 years, worse than many end-stage cancers.

PAD also imposes a substantial economic burden on healthcare systems due to the high costs of hospitalisation, multiple procedures, prolonged stays, eventual amputations, and rehabilitation, along with dependence on social care. Around 3,688 major lower-limb amputations are performed each year due to PAD[7] at a cost of £28,000 per procedure[8], and it is estimated that managing CLTI costs the NHS £244 million per year.[9] There are also concerns about the risk of those with PAD becoming economically inactive and unable to work.

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[3] https://vascularsociety.org.uk/_userfiles/pages/files/qips/best-practice-pathwayt-for-pad-march-2019.pdf
[4] https://cks.nice.org.uk/topics/peripheral-arterial-disease/background-information/risk-factors/
[5] https://jvsgbi.com/long-term-outcomes-of-major-and-minor-lower-limb-amputation-eight-year-retrospective-analysis-from-a-single-tertiary-referral-centre/
[6] https://www.jvascsurg.org/article/S0741-5214(02)75289-0/fulltext
[7] https://www.vsqip.org.uk/reports-publications/2024-nvr-state-of-the-nation-report/
[8] https://www.england.nhs.uk/publication/2022-23-national-cost-collection-data-publication/
[9] https://academic.oup.com/bjsopen/article/8/5/zrae099/7759873

Case study: 5 worst affected ICS areas for lower-limb amputations due to PAD

1. North East and North Cumbria - 390 amputations from April 22 - March 23

2. Humber and North Yorkshire - 226 amputations from April 22 - March 23

3. Greater Manchester - 207 amputations from April 22 - March 23

4. West Yorkshire - 196 amputations from April 22 - March 23

5. Lancashire and South Cumbria - 196 amputations from April 22 - March 23

Source: Hospital Episode Statistics 2022-2023

Identifying the current challenges in PAD diagnosis and treatment

Lack of awareness
One of the major themes identified during the roundtable is the current lack of awareness and understanding of PAD, not only among patients and the general population, but among clinical peers in both primary and secondary care.

Significant time and resources have been dedicated to disease awareness campaigns for other life-impacting diseases, such as cancer and stroke but these have overshadowed PAD despite limb ischaemia having a worse prognosis than cancer. Attendees agreed that PAD lacks the emotional impact of the other conditions as a direct result of its lack of investment. In addition to its lack of focus from the NHS, reducing waiting lists for vascular diseases including PAD have not had the focus and attention given to other similarly impactful conditions.

Due to the lack of awareness, patients often present to primary care several times before they are referred, making their prognosis and stage of disease much worse before they meet with secondary care vascular teams.

Diagnostic challenges
However, identifying PAD presents a challenge, as there are no rapid, simple diagnostic tests able to identify and screen for the disease. This becomes especially challenging if a patient is asymptomatic at the time of presenting to the GP - and exacerbates the issue of patients presenting to GP with late stage PAD.

Lack of NHS resources
It is no secret that the NHS is suffering from limitations on its resources and capacity, which has a direct impact on ensuring timely access to diagnostic, treatment and rehabilitation services. The NHS resource challenge impacts every level of the health system. In primary care, which is the first point for diagnosing and referring suspected PAD, there is a lot of pressure and limitations to appointment times, which is exacerbated by limited GP education on PAD to accurately diagnose and refer. Those who are referred are often at late stage PAD, which is easier to identify and refer, however patients are then faced with long waiting lists - meaning some patients are very unwell by the time they get to secondary care.

Within this wider context are the challenges with the utility and application of new medical technologies across the NHS. The current technology deployed in the NHS is outdated, and better access to technology and theatres is needed to improve PAD patient outcomes.

Inequality in accessing treatment between hospitals and regions
A large part of the roundtable discussion focused on the severe disparities in accessing resources and technology

between different hospitals and regions. This can subsequently lead to variations in patient outcomes, resulting in a greater proportion of amputations taking place in the North and Midlands.

According to data provided by the APPG on Vascular and Venous Disease, amputation rates in Northern England are 30% higher compared with the South.

To exacerbate the problem, there is inequitable access across hospitals in the UK to medical technologies to treat PAD. Some trusts and hospitals have more advanced technologies, such as IVL therapy, while others lack the resource and are left with limited to no treatment options for late stage PAD patients.

It was widely agreed that best practice excellence should be scaled up across the country. Disparities in access and availability of treatment is not just limited from hospital trust to hospital trust but it differs from hospital to hospital.

Greater Manchester and Leicester were highlighted as areas where exemplary service programmes are in place and where amputation rates have fallen. The PAD-Quality Improvement Framework, which is supported by the Vascular Society of Great Britain and Ireland, and the Circulation Foundation, aims to reduce delays in assessment, investigation, and revascularisation in patients with CLTI, and in turn amputation rates.

Patients with diabetes versus patients without diabetes

Whilst there is considerable overlap between diabetes and PAD, patients with diabetes have disproportionate access to services due to greater disease awareness and focus. The focus on diabetes has led to a strategy that has embedded inequality into the system. We need a different commissioning strategy. It was discussed and recommended that if patients from both the diabetic treatment pathway and the non-diabetic (PAD) treatment pathway were assessed by 'risk', rather than 'diabetes only' - a larger number of amputations could be avoided - lowering the inequality of access to care.

Lack of community-based care

The challenges around community-based care for PAD are two fold: there is a lack of education and awareness among nurses and at-home carers who are unable to identify the signs of PAD, and current community-based approaches to managing and treating PAD are inadequate, exacerbating the delay in referral and the onset of disease in patients.

Parliamentarians, clinicians and patient groups agreed that there needs to be immediate action from Government and the NHS to recognise PAD as a top priority and introduce a workable and effective strategy connecting community care, primary care and tertiary treatment to address the rising number of limb amputations across England. A simple way of doing this is to include PAD within the cardiovascular strategy and widening access to foot clinics by having a 'high risk' rather than 'diabetes only' approach to foot ulcers.

The Manchester Amputation Reduction Strategy (MARS)

Background
600 lower limb amputations are performed annually in Greater Manchester, of which half are preventable. Across Greater Manchester, MARS aims to reduce major limb amputations through the development and implementation of a MARS Commissioning Strategy. This 'whole systems' approach integrates multiple services, pathways and cultures to deliver population-based service transformation.

By better linking public health services with clinical pathways, MARS has been able to:

1. **'Diagnose more'** - raise capabilities and confidence of community nursing and podiatry teams to perform non-invasive vascular assessments.

2. **'Reduce inequality more'** - level up access for all lower-limb ulcers to the diabetes standard.

3. **'Make every contact count more'** - use Public Health Screening programmes to case-find undiagnosed conditions of concern, such as PAD.

Results
In the Salford locality, MARS delivered a 42% reduction in total amputation number (31.4% diabetes reduction and 53.3% non-diabetes reduction) over 6 years, with overall prevalence reducing 46% by 2021/22 (33.5 to 18.0).

Source: https//www.themarsproject.co.uk/

The case for greater Government recognition and investment

- **Potential to improve patient outcomes:** Earlier detection of PAD and improved access to timely interventions will potentially improve patient outcomes, including reduced amputation rates, better quality of life and reduced mortality.

- **Cost savings:** Early interventions including exercise programs, better medical management of cardiovascular risk factors and earlier revascularisation could help prevent the disease advancing and avoid costly complications, such as multiple hospital admissions, repeated revascularisation procedures, major amputations, and prolonged hospital stays, helping to reduce costs and free up resources in the health system.

- **Public health benefits:** Greater public awareness of PAD, its risk factors and the importance of early intervention could reduce the prevalence of PAD and avoid long-term complications. PAD often presents earlier than cardiac disease and thus earlier recognition and medical treatment will improve cardiovascular deaths.

- **Economic productivity:** Improved management of PAD could help enable individuals to remain active, live well and be productive members of society, which is beneficial to the economy.

Recommendations for Government and NHS investment

- **Dedicated National PAD Strategy** Launching a dedicated national strategy to improve the diagnosis, treatment and care of PAD. A new National Clinical Lead for PAD should be appointed to oversee the programme, and there must also be accompanying commissioning recommendations and guidelines to operationalise the programme. This would demonstrate the Government's recognition of PAD as a major long-term condition and its ambition to improve outcomes for patients.

- **Public awareness campaign:** Launching a national campaign in collaboration with patient organisations to improve public education and awareness of PAD, its risk factors and the importance of early intervention, including foot checks and preventative strategies. This will help inform patients of potential symptoms and encourage them to seek treatment or advice from GPs early on, and give them the tools they need to have conversations around PAD with their clinician.

- **Clinician education:** Improving education and training for healthcare professionals at primary-care and community-care levels, including the importance of early intervention and recognising symptoms. This will help improve early diagnosis and timely referral to secondary care. This includes prioritising patients with comorbidities and those considered 'high risk'.

- **Improved clinical pathways:** Designing and implementing more efficient pathways - from diagnosis through to community care - to deliver comprehensive disease management, will improve patient outcomes and minimise strain on health resources by reducing the risk of complications. These pathways should consider 'high risk' patients as well as patients with diabetes to lower care inequalities.

- **Community care:** Encouraging an effective community-based approach to diagnosis and treatment can help reduce waiting lists and lower the demand at the front-end. Improved community care can also help patients manage their PAD better, ensuring they remain active and live well.

- **Diagnostic capabilities:** Introducing integrated diagnostic pathways, including the use of rapid access community-based clinics and neighbourhood services, will help ensure timely diagnosis and better management of PAD.

- **Ending treatment postcode lottery:** Prioritising PAD within current and emerging national frameworks for improving quality and outcomes, including providing national benchmarking and guidance on treatment pathways and treatment options for patients with PAD to avoid unnecessary limb amputation, using big data sources such as the National Vascular Registry (NVR). This should provide data for research and audit purposes freely, via easy to navigate approval pathways.

- **Adoption of technologies:** Encouraging national procurement, and improving access and funding routes for the adoption of innovative technologies, will help facilitate safer, faster, and earlier diagnosis and treatment of PAD**.**

- **Research and innovation:** Prioritising funding for research and innovation in PAD diagnosis and treatment to improve preventative strategies for patients with PAD, including targeted commissioned calls relating to PAD research via the National Institute for Health and Care Excellence (NICE).

- **Data collection and analysis:** Improving data collection and analysis to track the prevalence and impact of PAD and monitoring effective treatment outcomes can be used to inform policy decisions, including the collection of innovative device data in the interests of patient safety as part of the recommendations of the Cumberledge report.[10] This should link to the NVR and other NHS datasets.

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[10] https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

Conclusion

Contributors from across the health system, including medical technology manufacturers, clinicians and patient organisations, have agreed on a vision for improving a) awareness, b) diagnosis and c) treatment of PAD. Addressing current challenges has arrived at an opportune moment for the Government and the NHS, as it looks towards moving care out of hospital and into the community, preventing serious health conditions and embracing technological innovation. By improving awareness of PAD and reforming pathways, patient outcomes across England could be significantly improved and the burden on the healthcare system caused by disease progression alleviated. The recommendations are vast but can be all implemented within a reasonable timeframe if the Government recognises the urgency of the situation and commits to ambitious reform. By implementing these recommendations, the Government can ensure that everyone in England has access to timely, effective, and equitable PAD care, from diagnosis through to treatment.

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Also in attendance were parliamentarians and a number of NHS trusts in England.

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