



Consulting

Peripheral Patients?

A call to action on Peripheral Arterial Disease

Tony Hockley PhD • October 2016 •



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1. PAD: Deadly, Spreading ... Treatable

“We have to highlight how dangerous this kind of disease is”¹

It is easy to regard peripheral arterial disease (PAD) as little more than a “leg problem”. PAD brings with it a high risk of death and disability, particularly leg amputation. It is a strong marker of more extensive arterial disease, providing a clear warning sign of serious problems. Someone who develops PAD faces a five to six times higher risk of cardiovascular morbidity or death compared to others without the disease[2]. These high risks exist even for those who do not have leg pain or other typical symptoms. Once PAD is diagnosed the risk factors associated with heart attack and stroke can be managed in the usual ways, and the specific vascular problems in the lower body are usually treatable. Lifestyle changes to increase physical activity and help smokers quit are particularly effective. The rewards to early intervention are high, reducing the risk of death from heart attack and stroke, and disability due to strokes or amputations.

Current estimates suggest that in the US alone 100,000 people a year have a limb amputated due to vascular disease, and the number is rising. These people are more likely to die in the following five years than those with cancers of the breast, colon or prostate[3]. In addition to the dramatic impact on the lives of people with PAD, and their families, if PAD has a late diagnosis or if its risks and symptoms are poorly managed then huge and unnecessary costs are incurred.

Following analysis of a sample of countries around the world² this paper highlights what appears to be a global, but avoidable crisis. Lives are being devastated by disability, and health systems are being strained by hospitalisations that could have been avoided. This state of affairs is both inefficient and inequitable, and will continue to worsen unless a rapid turnaround is achieved. This is a topic that is central to the financial challenge that health systems face and provides a clear test of their ability to change.

Too often it seems that care revolves around established health system structures (and divisions) rather than around the patient and their outcome. These structures include professional boundaries, funding streams, and administrative processes and measures. All present potential barriers to good practice. In other disease areas these barriers have been overcome in many countries, particularly in relation to tackling some cancers and improved care for stroke, for example. It is a matter of priorities.

It is clear that PAD lacks prioritisation within health systems. This research shows that knowledge processes and incentives that are essential to the delivery of good care are almost universally insufficient in comparison to the impact of the disease. There are, however, localised examples of improvements in PAD diagnosis and treatment, driven by committed local leadership. When combined with evidence from other areas of health care improvement it may be possible to identify useful proposals for change.

The lack of priority belies the fact that the need for action is urgent. As already noted, PAD is associated with a high risk of death and disability from cardiovascular events if the underlying risk factors are neglected. The case for prioritisation is both social and economic. Social systems are being severely strained by demographic change, as chronic care needs impose new and growing burdens on families, the workforce, health and social care providers, and insurers.

From a health system perspective the ambition must be to avoid hospitalisation of people with PAD. Hospitalisation often accounts for the majority of health spending associated with PAD, and in some

¹ Participant, Rome Roundtable

² The study focused on Denmark, England, France, Germany, Italy, Scotland, Spain, Sweden and Wales, but also with specific investigation of Australia, China, Norway, Russia, and the USA. The results of these literature searches are summarised in an annexe to this paper.

countries this can be higher than three-quarters of total spending on the disease[4]. The financial benefit of effective management of PAD as a chronic condition is very clear. The financial risk from a continued failure to do so is also very clear.

PAD is closely associated with age and with the prevalence of diabetes; the World is facing a period of rapid growth in the population aged over 60 years. In China, for example, the percentage of the population aged 60 or older is forecast to more than double by 2050, from 15.2% to 36.5%[5]. Even though the total population of many developed countries is forecast to decline, this shift in the age demographics means that the 60+ population will rise nevertheless from 901 million in 2015, to 1.4 billion by 2030 and 2.1 billion by 2050. On this basis alone, **even if the prevalence of PAD remained the same the number of people with PAD could rise from 202 million to more than 300 million by 2030**[5]. Alongside this growth in the elderly population, according to the WHO, the World is also facing an “epidemic” of obesity and diabetes[6-9], across the full range of countries and age groups [10].

There appear to be major barriers to achieving a significant win-win for patients and health systems:

- **Poor awareness and knowledge of PAD and cardiovascular risk.** It appears that the lower extremities lack the attention given to the heart and head, despite the fact that PAD is a good marker of more extensive atherosclerosis and strongly associated with mortality and morbidity, and that the costs of delayed intervention are very high.
- **Poor care co-ordination.** A common divide between vascular surgery in hospital and the local management of risk factors, including self-care, inhibits good disease management and a patient-centred care pathway.
- **Ineffective levels of treatment.** Even where PAD guidelines exist there is evidence of significant under-treatment against these, particularly where good practice incentives are either lacking or counterproductive.

Examples of improving practice do exist, and some of these are highlighted in the paper. Physician incentive schemes appear to have failed to adapt to the changing nature of the health challenge, favouring hospital-based treatment over primary and secondary prevention.

“We know that PAD is an illness which has very severe outcomes. Patients have high cardiovascular morbidity and mortality risk, and we have to improve that. That is our mission”

Participant,
Rome Roundtable

2. Familiarity breeds contempt?

PAD is a presentation of arterial atherosclerosis, in which plaque builds up in the arteries carrying blood to the limbs, head and organs. The build-up of plaque reduces the capacity of the arteries to carry blood, so that the oxygen supply to the affected parts is compromised. Whilst this might cause localised pain (or even gangrene) in an affected limb, the presence of PAD also indicates a significantly increased risk of coronary heart disease, heart attack, stroke, and mini-strokes[11, 12]. This is neither complex to understand, nor new.

The irony of PAD is that it is neglected *despite* being well-established in medicine, well-known, and common throughout the world. Perhaps it lacks priority because of the association with old-age, reflecting a general prejudice against the elderly or the pursuit of efficiencies when faced by elderly people with co-morbidities[13]. Perhaps because it is prevalent in smokers and diabetics, and suffers from a general medical and public disapproval of “self-inflicted” disease [14, 15]. Or it may be that the lower body is simply regarded as much less vital than the heart and head, and symptoms that appear there are more likely to be ignored whatever their consequences[16]. This hypothesis is supported by research involving “healthy” people aged 50 to 75 selected by ABI random screening showing asymptomatic PAD. Mundane reasons for dropping out of this randomised controlled trial (RCT) into Aspirin for Asymptomatic Atherosclerosis (AAA), included assertions that “*it’s not too serious*” or that it did not warrant the perceived risk associated with low-dose aspirin[17].

Another explanation for neglect may also be, of course, that health systems have developed over the years with natural divisions between the parts of the human body and are, therefore, ill-equipped to manage a disease that has local symptoms but systemic effects. In the case of people with diabetes or chronic kidney disease, at high risk of PAD and associated cardiovascular events, it is probable that diagnosing and treating PAD is lost amongst more “immediate” care priorities in these complex cases.

Whilst all of these explanations are credible, it is extraordinary that the disease has not conquered these problems in the many years since it was first identified and treatments developed for its symptoms and risk factors. An understanding of peripheral arterial disease, its symptoms and contributory factors is well established. As far back as the nineteenth century a veterinary account of a horse that went lame when exercised, only to recover at rest, was recognised by the Parisian doctor Jean-Martin Charcot as similar to a human case involving the “intermittent claudication” of the abdominal aorta [18, 19]. This was investigated experimentally for the first time in the 1920s[20]. Then in the 1930s Lewis, Pickering and Rothschild hypothesised that compromised blood flow would explain the pain experienced during exercise, and by the end of the 1930s the role of oxygenated blood in the removal of lactic acid from muscles during exercise was identified, as was the potential of insulin injection to reduce the effects of intermittent claudication[21].

Despite the considerable scientific knowledge of PAD that has developed over many years, including measures to prevent and treat it, the condition still appears to be subject to poor clinical awareness and widespread sub-optimal standards of care, particularly in secondary prevention amongst diagnosed patients[22] when judged against current guidelines. Leading guidelines with an international reach include those issued by the European Society of Cardiology in 2011[23] and by the American Heart Association and American College of Cardiology in 2005[24].

Despite the considerable scientific knowledge of PAD that has developed over many years, including measures to prevent and treat it, the condition still appears to be subject to poor clinical awareness and widespread sub-optimal standards of care.

The ESC Guidelines identify the major PAD risk factors, particularly for lower extremity arterial disease (LEAD) as smoking and diabetes, although the strongest association with diabetes is for the most severe form of LEAD. The Guidelines also note that epidemiological studies show a disease association with hypertension, high levels of total cholesterol, and high levels of LDL-cholesterol. A US study showed the ratio of total/HDL-cholesterol as the measure with the strongest association[23].

As Marrett et al noted from a recent study covering a population sample of five European countries and the US, the burden of PAD on those affected is high, both in terms of mortality and morbidity[25].

Analysis by NICE in England found that around 10 to 15 percent of people diagnosed with PAD die within five years from cardiovascular causes, and additional to this 20 percent survive a cardiovascular event such as a heart attack or stroke[26-28]. A study of 16,440 people with a PAD diagnosis in the Canadian province of Saskatchewan found a reduction of 6 to 7 years of life in comparison to healthy individuals, using data spanning a 20 year period between 1980 and 2000. The study also demonstrated a particularly high mortality rate for PAD patients if they suffered an atherosclerotic event, such as stroke or myocardial infarction, in comparison to people included in the study with other forms of atherosclerotic disease[29].

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3. More common than you think

There are more than five times as many people in the world living with PAD than with HIV [30, 31]. Not only are numbers rising, but this traditional illness of old age is on the increase in the working-age population[30].

Many people with PAD are undiagnosed, including many deemed asymptomatic. Nevertheless, recent estimates are that **there are 202 million people with PAD worldwide** [32] and that the developed country prevalence is 12% in the adult population, and rising with age. [33, 34]. Studies have shown, for example, that around 20% of people in England and Sweden aged 60 years have some PAD [26, 35]. The disease is usually diagnosed by measuring the difference in blood pressure between the ankle and the wrist, known as the “Ankle-Brachial Pressure Index” (ABI or ABPI), and where this test has been widely used this has revealed that the majority of people with PAD are asymptomatic[36], thus a substantial variation in estimates of prevalence is to be expected.

Prevalence estimates vary significantly where they are available and broadly comparable. The association with age is, however, well-established, so that **countries with an ageing demographic profile can also expect an increasing prevalence of PAD**. The Italian Longitudinal Study on Ageing, for example, found a 43% increase in the number of people with PAD aged 75 or older between 1992 and 2002[37]. The global population aged 60 or over is growing at an annual rate of 3.26%. Thus the number of older people in the World is forecast to grow from 901 million in 2015 to 1.4 billion by 2030 and 2.1 billion by 2050[5].

Even within countries data on prevalence can be highly variable. Spain, for example, reports geographic variations in prevalence in the population aged 55 to 85 years between 4.5% and 9.5%, and nationally between 10.2% in men and 6.3% in women [**Annexe – Spain**]. Across the United Kingdom prevalence across the whole population varies between 0.4% in London and 1% in the North East[38]. There appears to be a different pattern of prevalence by gender in China, with most areas that were included within a recent report

suggesting a higher incidence amongst women than men, but with a combined rate of 16.4% in the over-60 population, and 19.4% in the diabetic population aged 50 or over[39]. Data for Russia reflect serious health problems in the country: Whereas 63% of patients admitted to hospitals in UK and Ireland with critical lower limb ischemia are aged 70 or older, in 2001 in Russia the equivalent proportion was just 24.4% [40].

The data demonstrate that PAD is present on a significant scale across countries, with some regional variations. Even where rates of smoking are in decline the expected reduction in prevalence will be offset by demographic shifts in the age profile of the population, and in many countries by rising rates of diabetes associated with rising rates of obesity.

4. Variable, inequitable Care

4.1 Diagnosis

PAD is a relatively cheap and simple condition to diagnose, initially by use of the ankle-brachial pressure index (ABI or ABPI): A check for difference in systolic blood pressure between the arm and the ankle, using a standard blood pressure cuff and a handheld Doppler[41]. Whilst relatively simple, and deliverable by a range of clinicians rather than just by hospital specialists or general practitioners, it does require training and practice [42-44]. Other approaches to PAD detection, including clinical examination and the use of cardiovascular risk factors, have been shown to be unable to detect patients with a low ABI, thus leaving them untreated until the disease becomes symptomatic or the patient suffers a cardiovascular event[42]. In some patients the use of a Toe-Brachial Index (TBI) is preferable, as the ABI can produce false normal results where arteries in the lower leg have wall calcification. This is common in diabetics and patients on dialysis, and the rarity of wall calcification in the blood vessels of the toe means that TBI can be the more reliable measure for PAD [45, 46].

In the development of guidance for the NHS in England the National Institute for Health and Care Excellence (NICE) assessed that any costs in implementing the requirements would be small, and outweighed from subsequent savings in treatment costs. The NICE cost analysis notes that the ABI measurement would be completed by a nurse or podiatrist whilst taking a clinical history, and that it *“may add between 5 and 15 minutes to the time needed”*[47]. Despite this there is wide variety in the testing of at-risk individuals. A study in Wales found that even amongst those 20% of general practices responding to a questionnaire 42% were using the ABI incorrectly [48]. An Italian survey found significant variation between local health agencies in the procedures used and in diagnostic capacity[49]. **In Sweden the diagnosis of PAD in primary care has been described as “uncommon”**[50], which probably reflects a generally low level of outpatient contact in the health system[51]. A study in Western Australia found significant variations in the use of ABI amongst podiatrists, despite a widespread understanding of its value. This study argued for clear guidance on techniques, training, and funding[52]. A French survey found that only a minority of GPs were aware of national ABI recommendations, and actual use was positively associated with education and training. Without specific reimbursement for ABI testing this was lost due to other demands on GP time.

Whilst population screening for PAD is not yet supported by evidence[53], targeted approaches may prove beneficial based on clinical prediction models[54]. It is certainly a first priority to improve the identification of those most at risk. For the future it is probable that diagnostic equipment requiring even less training and expertise than the current handheld dopplers for ABI (or TBI) measurement will become more widely and cheaply available[55].

4.2 Treating Risk Factors

Good practice in PAD is concentrated on interventions that support smoking cessation and regular exercise, given the evidence of significant benefit in the diagnosed population. In the past PAD has tended to be treated as a localised problem, but the association with cardiovascular mortality has led to the creation of international guidelines that recommend more systemic atherosclerotic risk factor therapy[56].

As with other forms of CVD, statin therapy for lipid modification, antiplatelet and antihypertensive drugs (ACE-inhibitors and β -blockers) form the basis of a strategy to avoid cardiovascular events. In one major study the use of simvastatin, for example, reduced the relative incidence of major cardiovascular events over a five year period by 19%. Clopidogrel and low-dose aspirin have each been shown to be effective anti-platelet therapies in the reduction of fatal and non-fatal cardiovascular events [23]. Modified-release dipyridamole is also used, as an alternative to aspirin or clopidogrel.

Despite the widespread dissemination of guidelines primary and secondary prevention are still weak and variable. Even in US Medicare patients who have been treated by revascularisation it appears that less than 70% of patients filled a prescription for statin therapy in the six months following their surgery. Patients older than 80 years, or black, or with a medical history of dementia were significantly less likely than others to be prescribed a statin[57].

Differences between professional groups appears to play a significant role in variation in the treatment of risk factors[57, 58]. The existence of national and international guidelines has limited effect. In the survey of GP practices in Wales mentioned above only half of GPs and 16% of nurses *“reported that patients with an ABI of ≤ 0.9 require aggressive cardiovascular disease risk factor modification (as recommended by current national and international guidelines).”*[48]

4.3 Treating Symptoms

Intermittent claudication can be treated by surgical or pharmaceutical intervention, by revascularisation surgery (using angioplasty, a bypass, graft or stent) or the prescription of one of the vasodilators, which include cilostazol, naftidrofuryl oxalate, pentoxifylline, and inositol nicotinate[59]. The 2011 European Society of Cardiology Guidelines reported promising results from the use of carnitine and propionyl-carnitine in initial trials, and some symptomatic improvement using Buflomedil in a study, but with side-effects that led to market withdrawal in Europe [23, 60]. In cases of critical limb ischemia, with chronic pain, opioids may be necessary for effective pain relief, even after revascularisation or amputation

4.4 Inequity within cardiovascular care

It appears that PAD pharmaceutical treatment lags well below the levels recommended in guidelines. Research in Denmark, for example, found that **patients who had been admitted to hospital with lower-limb PAD were 10 times less likely to received subsequent preventative drug therapy than myocardial infarction patients**[61]. The ATTEST study in France revealed significant under-treatment: Only 13% of PAD patients included in the study received ACE-Inhibitors, statins and anti-platelet agents, compared to 30% of patients with coronary artery disease or stroke [62]. These studies date from the turn of the millennium, and the care of all cardiovascular diseases will have improved significantly since then. Nevertheless a more recent analysis from Germany still suggested that only half of PAD patients received anti-platelet agents, compared to two-thirds of those with coronary heart disease. Just 23% received statins, compared to 46% in CHD[63]. and there is evidence that even amongst diabetics, at high risk of CVD events and amputations, basic tests are neglected [64].

The authors of recent research into vascular hospitalisations in France and Germany concluded that **PAD is: “undertreated and under-recognised, despite the fact that it shares the same underlying atherosclerotic**

process and risk factors as CAD and CVD” [65]. Similarly a study of the Swedish health system also found in vascular surgery that: *“a large proportion of patients did not receive recommended secondary preventative drug treatment”*[66]

Amputation rates too show dramatic inequities; by location, race, and wealth [67-69]. In 2014 the National Health Service (NHS) in England was revealed to have regional rates of amputation between 30% and 44% higher than those in London [1]. Analysis of lower limb amputations in people with diabetes across OECD countries has suggested not only that there is dramatic variation between countries, but also according to whether a health system is largely funded through taxation or by insurance[70].

5. Poor Care is Expensive Care

PAD is a major cause of disability through its direct impact on the ability to walk, and these impacts are increasing worldwide even whilst amputation rates are reducing in many countries[12].

It is clear that hospitalisation accounts for the vast majority of PAD treatment costs. In US studies the share of total annual PAD patient costs attributable to hospital stays was calculated at 75%, out of an average annualised cost per patient of around \$6000[4]. For France the costs of hospitalisations appear to account for 40 to 50% of the total amount reimbursed to claimants by the social insurance system [71, 72]. An analysis of reimbursement claims for hospital treatment in Germany identified costs rising to €2.56bn in 2009, accounting for almost 5% of total hospital costs [73]. In Sweden too the majority of the SEK 1bn annual cost (2005) relates to inpatient care[74]. This highlights the potential value of effective preventative strategies in order to avoid the hospitalisation of PAD patients.

The share of total annual PAD patient costs attributable to hospital stays was calculated 75% out of an average annualised cost per patient of around \$6000[1].

Separate to the costs to fund health system, PAD has significant impacts upon individuals and households, affecting daily activities and creating significant support needs. The most common impact is the pain caused by intermittent claudication during activity, but in more severe cases pain is chronic, even at rest, and artery obstruction (critical limb ischemia) threatens ulcers and gangrene in the affected limbs, leading ultimately to the need to amputate. A study of US and European data found a **mean level of self-reported work absenteeism amongst those with PAD almost four times that of the age-match population without the disease, and a level of activity impairment around twice as high**[25]. The authors note that:

“Predominantly, due to the functional limitations caused by claudication patients with PAD report significantly lower health-related quality of life compared with the general population on every Short Form-36 (SF36) domain”[25].

Not only are lower limb problems closely associated with issues of disability and mobility, but are also strongly associated with placement in a nursing home [75], a major and growing expense for social security and health systems. A recent study for the European Commission predicted increases in long-term care costs that will threaten the sustainability of European social security systems, reinforced by an ongoing shift from informal to formal care, and rising costs within this labour-intensive industry. The report highlighted the value of policies that reduce severe disability, so that dependency is postponed alongside the increase in life expectancy[76].

The impact of PAD on health-related quality of life is now well documented, and the severity of impact rises with the severity of symptoms, independent of other risk factors. The adverse impact is reported even in people who are diagnosed as having borderline PAD[77].

There is some evidence of inequitable access to care, by geographic location within a country, wealth, ethnicity, and gender [68, 78, 79]. Whilst for most health systems the cost of treatment mostly is covered by the health service, social or private insurance, this is not universal. In China, for example, the high personal costs of CVD care can drive households into poverty when insurance coverage is insufficient [80, 81].

It is clear from the evidence that preventative care that avoids hospitalisation and surgery has significant financial benefits to health systems and patients[82]. In one practical UK example, a hospital investing £33,000 annually in a multidisciplinary foot care team saved seven times as much in reduced amputations[1]. For many countries demographic change means that the population will need to be productive for longer, remaining active and independent for as long as possible. Recent data for the UK show the proportion of those aged 65 and over who work to have doubled since 1992, with a particular (and rising) share of part-time self-employment amongst those aged over 70 years and working. Health systems discrimination against the elderly is, therefore, unsustainable when it neglects simple steps to prevent disability.

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If countries are to realise visions for “productive ageing”[83], in which older people can participate in economic and social action, then improvements in the prevention, diagnosis and treatment of PAD will play an essential part in achieving this ambition. There is still a long way to go in meeting the 2002 commitment in the UN Madrid Declaration on Ageing, for health systems to: “*design early interventions to prevent or delay the onset of disease and disability*”. [84]

PAD is not, of course, confined to the elderly, and most worryingly the disease appears to have a wider range of causes in the young, presenting exceptional challenges for diagnosis and treatment[85]. The disease also progresses most rapidly in patients who experience symptoms before the age of 45, and suffer the worse outcomes than older patients [12, 86]. Analysis of the health insurance claims database in Japan showed that PAD patients below the age of 65 incur substantially higher costs than their peers, and suffer dramatically higher rates of heart attack and stroke within a year. Amongst working age diabetics with PAD these costs and event rates were also much higher than those for other diabetics, including an elevated need for vascular surgery and amputation[87]. The World Health Organisation and others have declared diabetes a global “epidemic”[88, 89] with the number of people affected worldwide quadrupling since 1980, with the global economic burden rising to \$1.7 trillion by 2030[90].

6. Stepping up

Over the years there have been numerous efforts to improve awareness of PAD amongst clinicians and the general population, usually led by specialist clinicians. In 2003, for example, the US National Heart, Lung and Blood Institute partnered with the American Heart Association and the Vascular Disease Foundation to develop an awareness campaign for PAD, and several campaign groups exist, particularly in the US and UK to promote awareness of vascular disease in general. Even in these cases, however, it seems that the activity

has failed to achieve a shift in understanding of PAD as a specific disease with particularly high risks and specific options for preventative care and treatment.

In 2010 the German Society for Angiology launched a promotional campaign on PAD involving German celebrities as ambassadors, targeted at the population aged over 50 years. The ambition of the campaign was not only to educate the public around risk factors and diagnosis, but also to enable the creation of local PAD networks of providers, physicians and insurers[91]. In 2012 the Italian association AmaVAs launched an awareness and self-testing tool for the general public, known as “FeeTest”[37, 92]. As yet there appears to be no evidence that such campaigns have succeeded in achieving a substantive improvement in awareness amongst clinicians and the public.

Such improvements have, however, been seen in several other disease areas, as evidence on effective care developed and policymakers became alert to the impact of substandard care due to poor awareness and increasingly inappropriate health system organisation. Advances in stroke and cancer care are the most obvious examples.

In England the National Health Service rolled out a system of free “health checks” for the over-40s from 2009, with national financial support and incentives for GPs. The NHS has also begun experimenting locally (with national financial support) with new models of care, attempting to begin to integrate primary and secondary care, using multidisciplinary provider arrangements and integrated budgets, with funding directed towards outcomes rather than activities.

In the socially deprived and ethnically diverse area of East London, GP practices, the local hospital and the social care system and voluntary sector have been brought together into a managed network[93]. As well as having a pooled “Year of Care” budgets, members of the local network are required to pool relevant data. The data system provides clinicians with a “dashboard” of performance, and strong financial incentives are designed to create a common focus on patient outcomes. PAD is included as a priority disease. Desired outcomes include clinical measures, the avoidance of hospital admissions, and the avoidance of permanent nursing home admission. By 2012 Tower Hamlets had already delivered a “step change” to become the top performing area in England across a range of measures, including diabetes and CVD. **The high level of achievement in Tower Hamlets has been ascribed to the managed networks approach and a decision to prioritise invitations for patients whose medical records suggested the highest level of CVD risk**[94] [Fig: East London Integrated Care]

Experimentation with payment systems that fund whole episodes of care, or “bundled payments”, are now quite widespread. These often do not serve to integrate preventative and curative services, however, so their scope to achieve improved outcomes may be more limited than their scope to discourage unnecessary costs[95]. Where funds are pooled across all forms of care, as in Medicare’s use of an “Accountable Care Organisation” (ACO) approach, there may be greater scope for preventative activity, although there remains some risk that ACOs may game the system[96]. Another example is the CMS five-year experimental “Million Hearts”[®] CVD risk reduction model, which provides Medicare payments for data-driven identification of the at-risk population and subsequent risk-stratified disease management. Payments of \$5 to \$10 per beneficiary follow achievement of outcome targets[97]. Although this is a limited, but large trial, it could well have a lasting impact on practice: “\$10 adds up quickly per patient ... once we put the ASCVD risk score into our practice, we’ll probably measure it in everyone for a very long time”³.

³ Participant, Rome Roundtable

More directly targeted changes to physician financial incentives are taking place in many countries, in order to shift the focus of activity towards prevention in general and, sometimes, to raise the profile of PAD within this. In France, for example, the publication of guidelines on lower-limb PAD and on anti-platelet agents broadly coincided with the introduction of a voluntary scheme of financial incentives. These include rewards for meeting targets relating to blood pressure and cholesterol in CVD patients, and for adherence to the French guideline intending to increase the use of aspirin as the preferred long-term anti-platelet agent [98]. Financial incentives have a complex track record, and need to be used with care if unintended consequences are to be avoided, particularly as something will usually be displaced by an incentivised activity, and an incentivised activity without personal clinical commitment may well be done badly as a response to a perceived loss of autonomy[96]. Financial incentives should not be expected to improve practice alone, but need to be part of a combination approach to motivate clinicians (and patients) that can be locally-owned[99].

“\$10 adds up quickly per patient...once we put the ASCVD risk score into our practice, we’ll probably measure it in everyone for a very long time”

Participant,
Rome Roundtable

England, Scotland and Wales have developed common clinical pathways for PAD. This progress may be due in part to effective pressure by the large patient groups Diabetes UK and the British Heart Foundation, which produce their own patient guides. Guidelines produced by the National Institute for Health and Care Excellence (NICE) provide the basis for targets within the GP system of financial incentives known as QOF⁴. This is, however, applied differently in each of the three countries. Alongside this the NHS in England and Wales each run their own patient information websites containing specific information on PAD.

The advantages of a combination approach were highlighted in the analysis of two outpatient registries in Canada, which did not show the significant levels of under-treatment seen elsewhere. The authors concluded that:

“Provision of the guidelines and an evidence base supporting the use of these therapies to participating physicians, as well as feedback on how physicians managed their patients relative to national averages, may account for the higher use of evidence-based treatment in our registries compared with prior studies”[100].

Service standards can be ineffective unless systems for monitoring and feedback are put in place and maintained, with local support. Such examples provide useful guides for future policy.

⁴ Quality and Outcomes Framework

7. Time for Action

It is clear that the neglect of PAD is a global phenomenon.

This failure defies simple explanation, given widespread evidence of the economic and social costs of care failures. It is precisely in such areas of disease that health systems are sowing the seeds of their own destruction, as demographic and lifestyle change brings their financial sustainability into question.

Urgent action on public and clinical awareness is needed, as well as fundamental changes so that the delivery of care is patient-centred, with a shared ambition to promote health rather manage the patient's decline.

7.1 Awareness

“Many doctors are not familiar with the diagnosis of PAD, so it is excluded from the grade score by cardiologists. That is the way to maintain the lack of awareness of PAD”⁵

It is crucial the evidence base for PAD diagnosis and treatment continues to grow. Much of the current evidence base for interventions in PAD come from subsets within broader studies, and further research specific to PAD could improve awareness of the disease and confidence in treatment options.

This does not excuse the fact that there so little public awareness of the disease [101], and widespread failure to follow current evidence-based good practice guidance. In the few examples that we have found of initiatives to improve the treatment of PAD patients there is a demonstrable case for **improved systems to support good practice, by providing performance feedback to clinicians**. There is also a **strong financial and clinical case to be made for the incorporation of PAD quality standards into physician incentive systems**.

“Many doctors are not familiar with the diagnosis of PAD, so it is excluded from the grade score by cardiologists. That is the way to maintain the lack of awareness of PAD”

Participant,
Rome Roundtable

Too often it seems that PAD is given a low priority because it does not appear in the head or heart. Professor Dr Schulte of the vascular centre in Berlin, Germany has argued that:

“These (PAD) patients often have leg pain rather than heart complaints. Thus the condition is taken less seriously by patients and physicians.”[16]

This attitude is illogical and dangerous. The ATTEST study in France found that physicians were underestimating cardiovascular risk in PAD patients, whilst overestimating their amputation risk[62]. To counter these prejudices it is vital that pressure is brought on health systems to ensure that PAD is placed alongside heart attack and stroke in discussions of cardiovascular disease, to firmly establish this **“prevention triad”**⁶.

“We should be talking to patients so they understand that if you have leg pain, it’s like chest pain. ‘If you had chest pain you wouldn’t wait to go to see your doctor. Why are you waiting when you have leg pain?’”⁷

⁵ Participant, Rome Roundtable

⁶ Participant, Rome Roundtable

⁷ Participant, Rome Roundtable

Improved service performance have been achieved through the use of the “spotlight effect”[102] that performance reporting generates. Feedback and monitoring provide a consistent reminder to physicians to ensure that a PAD diagnosis is followed-up on a consistent basis. One US study found that whilst 83% of patients were aware of their diagnosis when asked, only 49% of their physicians were also aware [103]. Significant efforts have already been made to raise awareness of PAD, most notably by the US-based Vascular Disease Foundation in 1998, which generated concerted efforts for public education around consistent messages. These included the “*Save a leg, save a life*” campaign which began 1999[104]. Whilst there has certainly been progress in the intervening years, it remains far too little given the level of care that is possible.

“We should be talking to patients so they understand that if you have leg pain, it’s like chest pain. ‘If you had chest pain you wouldn’t wait to go to see your doctor. Why are you waiting when you have leg pain?’”

Participant,
Rome Roundtable

It seems unlikely and makes little sense that raising awareness and knowledge of PAD should be a singular campaign within the vascular community. The close associations with other forms of atherosclerosis and with diabetes and kidney disease [105, 106] should form the basis of a more concerted and complete effort on cardio-vascular health. The recent WHO Global Report on Diabetes, for example, estimated that rising obesity rates particularly are pushing up the prevalence of diabetes, from 108 million people in 1980 to 422 million in 2014 [90]. Nevertheless, world leaders committed in 2010 to achieve a 25% reduction in overall mortality from CVD and diabetes by 2025[80].

Dramatic variations in care and the widespread failure to follow guidelines should have motivated change by now. Certainly, something more needs to be done if guidelines are to have greater effect, particularly in primary care[107]. It may well be that guidelines from national and international groups are too distant to gain local ownership, and efforts to improve PAD awareness may need to be combined with practical efforts to develop local adaptations and local clinical leadership.

Disease awareness “days” are a popular tactic, but it is perhaps as a result of this popularity that their impact is questionable[108]. To break through this crowded environment a core, memorable message is essential. PAD highlights stark inequalities in care, so that avoidable deaths, amputations, and disability are concentrated. Awareness of health inequalities lie at the root of some of the biggest changes seen in attitudes to public health, and have provided the impetus for change. Awareness of the burden of HIV in developing countries, for example, led directly to global efforts to address legal issues around access to medicine[109], not just in HIV. The combination of a concern for social justice alongside a personal fear of the disease is a strong motivator for education and change. The use of amputation maps as a mark of service failure has proven to a useful tool for gaining public attention[1, 110], although a common metric for ischemic amputations would be required for robust, comparable mapping.

It is sadly true that people respond more strongly to the fear of a loss than to the prospect of a gain[111]. Death and other extreme outcomes are, therefore, more potent in raising public awareness than the potential for sustained healthy living. In PAD, however, these outcomes are highly relevant, as they are unfortunately common outcomes from poor care.

7.2 Patient-Centred Care

PAD brings high cardiovascular risks to patients, and can cause pain and disability in the lower limbs. It is also a very significant co-morbidity in diabetes, chronic kidney disease, and other chronic diseases. Because of this web of clinical relationships the disease is particularly susceptible to the “silo effect” of health systems; it appears that the disease is often managed solely as a vascular condition for treatment by surgery, or that there is no single point of contact for the patient in the care pathway, where this exists, to take full ownership of the patient and their outcome. Whoever takes ownership, the presence of a clear and accessible point of contact would do much to enable patient-centred care.

In different settings the owner of the PAD pathway will differ, and this owner might not be a doctor. Indeed, nurses may be more willing to follow guidelines than doctors[112], and it may be that non-medical health professionals are best able to take a local leadership role in PAD. “Implementation of guidelines shouldn’t just be left to doctors ... It is 2016. We need to be more creative and have some decision support built into how we work”⁸

Experience with registries and managed networks highlight the value of services centralised around the patient. **The idea of a “one stop clinic” [56] to simplify the complexity of the care pathway has been shown to have considerable merit.** There is otherwise too great a risk that the delivery of effective care is simply too challenging for both the clinicians and the patient.

The WHO has argued that diabetes, in particular, requires “an organized and integrated health system” to deliver optimal care[90]. A review of evidence in Scotland found that “devolved community care” was vital to good disease management in PAD. Improved organisation of the care pathway should raise efficiency and outcomes, which are crucial given the severe financial constraints on health systems: **“It might be things like the organisation of services to try and avoid duplication, to try and make referral more efficient, to have multidisciplinary centres in order to have less qualified staff dealing with the simpler issues like prescribing anti-platelets ...”**⁹ An integrated team should also enable a new focus on preventative care: **“People are very concerned about the use of intervention for symptoms. People are looking to reduce costs now. One way to do that is to say you have to achieve certain things before you’re a candidate for vascularisation. Even if you delay vascularisation that’s not necessarily a bad thing and it will reduce cost”**.¹⁰

“Implementation of guidelines shouldn’t just be left to doctors...It is 2016. We need to be more creative and have some decision support built into how we work”

Participant,
Rome Roundtable

Evidence from the US Medicare system highlights the major role that financial incentives can play in shifting the balance of care from hospital to the community setting. In response to the high costs of inpatient care Medicare increased physician reimbursement rates for revascularisation in 2008 for outpatient treatment: Between 2006 and 2011 inpatient interventions fell by 28%, while hospital and physician office-based outpatient activity grew by 24% and 530% respectively[113]. In the UK the inclusion of one or more PAD measures within the quality indicators included in the primary care physician payment system has led to significant improvements in adherence to good practice with regard to the activities that are included. The 2009 NHS introduction of a five-yearly basic health check for individuals aged 40 to 75 is expected to further improve the diagnosis and care of those with vascular disease.

⁸ Participant, Rome Roundtable

⁹ Participant, Rome Roundtable

¹⁰ Participant, Rome Roundtable

One of the most striking examples of progress comes from East London, as mentioned previously. By redesigning care around the patient rather than around the structures of the local health service, and prioritising those most at risk, considerable improvement became possible.

In conclusion, therefore, it seems that the search for evidence must continue, so that knowledge and awareness can increase, but there also needs to be a shift towards care that is centred on the patient, and routinely measured.

8. Five Steps for PAD

The evidence gathered for this report suggests five key actions to build a better future for patients with PAD.

1. Campaigns highlighting inequalities in mortality and amputations
2. Collaboration with Diabetes, CVD, and kidney disease campaigns
3. Education and training modules for primary care providers, supported by robust incentive and performance feedback systems
4. Research into the potential benefits of facilitated diagnosis
5. Research into the impact of integrated care on disease outcomes

It is by no means accidental that the first two relate solely to awareness. Unless the scale and severity of the problem is understood the other three actions will prove futile. PAD is not a new disease, it is simply neglected. It shares common risk factors and treatment for risk factors with heart disease and stroke. PAD is an important marker of more extensive arterial sclerosis, carrying exceptionally high risks. If this is understood and acted upon then many lives and limbs can be saved. For much too long PAD appears to have been dismissed as a vascular problem of the lower body. Like cancer, PAD “spreads”. There seems to be little reason why it should not have similar public engagement. As life expectancy increases, and the spread of obesity and diabetes continues, PAD will increasingly affect people who will otherwise have working, active lives ahead of them. It is a readily avoidable crisis of demographic and social change.

With better understanding will come better potential for the successful redesign of clinical training, incentive systems, and care pathways. This report has highlighted some examples of improved care, delivering much better outcomes, all of which are rooted in a shared understanding of the disease and its risks.

It is rare in health policy that so much can be changed simply through better use of existing knowledge, and the implementation of existing policies. The potential for improvement that will benefit lives, health systems and economies seems huge, and it is shocking that the track record is so poor.

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A Note on Research Methodology

This policy paper is written by Tony Hockley, an economist specialising in health systems analysis. The paper draws upon a literature search undertaken by the author and a team of researchers, relating to “peripheral arterial” and “peripheral vascular” disease. The searches were conducted mostly within the Summon search engine, with an emphasis on peer-reviewed sources. The search strategy covered the disease in general terms, but with specific searches for the selected countries. For Russia, China, Italy and Germany researchers were recruited with appropriate language skills to undertake and report on their country-specific searches. In August 2016 AstraZeneca convened an evening roundtable of international PAD experts, held in Rome during the Congress of the European Society of Cardiology. The roundtable discussed a draft of the paper’s Executive Summary, and several participants provided follow-up commentary by telephone in the days following the roundtable.