

# Dragging their feet:

THE COST OF SUB-OPTIMAL TREATMENT FOR PATIENTS  
DIAGNOSED WITH PERIPHERAL ARTERIAL DISEASE

VERSION 2



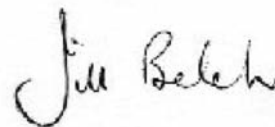
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Target PAD is a multidisciplinary group of expert clinicians, working to improve outcomes and quality of life for patients with peripheral arterial disease (PAD).

PAD is an important and common condition, which is currently under-diagnosed and under-treated worldwide and in the UK. Target PAD's mission is to improve education and awareness of the disease among patients, health professionals and policy makers, resulting in PAD being given an appropriate proportion of health service resources and funding in both secondary and primary care.



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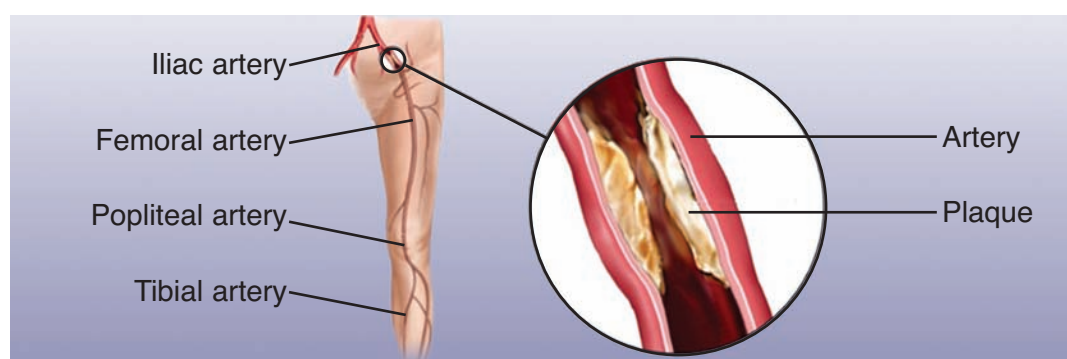
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# 1. Introduction

Along with heart disease and stroke, peripheral arterial disease (PAD) is the third strand of atherosclerosis, a disease affecting blood vessels. Unlike heart attacks or stroke, PAD is relatively unrecognised and, as a result, suffers by comparison in appropriate diagnosis and treatment.

## Causes, symptoms and effects of PAD

PAD is the narrowing of the arteries (blood vessels) in the body and mainly affects arteries that transport blood to the legs. This narrowing of the arteries is caused by atheroma – fatty patches or 'plaques' that develop inside the arteries, reducing the flow of blood.



PAD develops gradually and can remain unnoticed for long periods. In many cases, it may be asymptomatic. The rate at which the disease develops can vary significantly depending on the individual and when the symptoms do appear they can contribute to a very poor quality of life for the sufferer.

Many people with PAD will not experience symptoms, for those who do cramp-like pain is normally the first. Also called “intermittent claudication”, it is fatigue, discomfort or pain in the muscles of the legs on exercise. To begin with the pain develops when walking up hills or stairs, and then as the disease progresses, symptoms occur when walking on the flat. Specifically, the pain often occurs in the calves, upper legs, buttocks or feet and is a signal that the muscles are suffering from lack of oxygen. Walking puts the muscles under increased strain, so that more oxygen and efficient blood circulation are required. However, this is not possible due to reduced blood flow in the narrowed arteries.

Failure to stop the progression of PAD leads to further deterioration of the blood circulation. In addition to pain when walking, people with the disease may experience pain even at rest, particularly at night, and other symptoms such as ulcers on the feet or toes.

Without proper blood flow, wounds cannot heal. Even a small cut will have difficulty healing. This could lead to infections and permanent tissue damage. In the worst cases, gangrene occurs and amputation may be necessary if adequate blood flow cannot be restored.

## The scale of the disease

In the UK, at least 720,000 people suffer from symptomatic PAD<sup>1</sup> and over 102,000 people are newly diagnosed with PAD each year.<sup>2</sup>

Approximately 5% of people over the age of 60 years – around 600,000 people in the UK – suffer from intermittent claudication as a result of PAD.<sup>3</sup> However, it is estimated that half of all people with PAD have no obvious symptoms; the first indication that they have PAD may be when they have a heart attack or stroke.<sup>4</sup>

Furthermore, in the UK, one in six people over the age of 55 years have some degree of PAD.<sup>5</sup> Incidence increases with age and, by the time they reach 70 years, around 15-20% of people will have some form of PAD.

Data taken in 1991 indicates that as many as 2.7 million people aged between 55 and 74 years in the UK may have PAD.<sup>5</sup> While this is rather old data, it merely serves to demonstrate the lack of focus on PAD in recent years and it is likely that today's figures would be even higher than the findings of this study.



## 2. How should PAD be managed?

Simple and effective treatments for the prevention of heart attack and stroke in PAD patients already exist and are routinely used by doctors in the treatment of coronary heart disease (CHD) and stroke. These include antihypertensives, antiplatelets, and cholesterol-lowering medicines, such as statins.

### Primary care treatment of PAD

For most patients, their GP will determine the combination of treatments most likely to maximise clinical benefit for each individual patient. Patients will also be offered advice on lifestyle changes which can also help reduce the risk of suffering from a cardiovascular event, e.g., smoking cessation and taking regular exercise.

The Target PAD group has produced an algorithm for best-practice primary care treatment of PAD. This represents the expert view of the optimal treatment pathways for patients diagnosed with the disease. The algorithm diagram is reproduced overleaf.

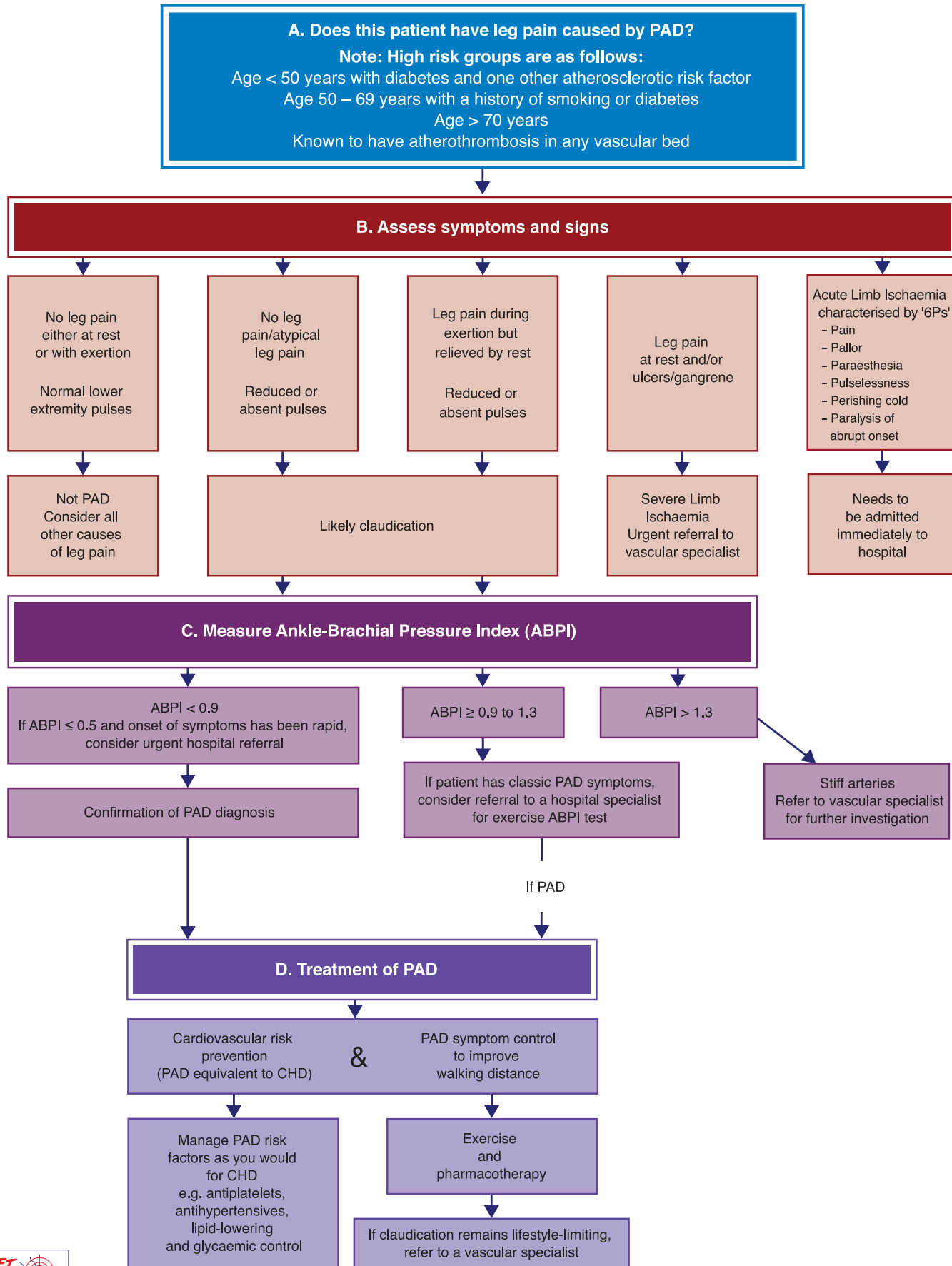
Clinicians are agreed that patients with PAD are a particularly high-risk group and aggressive management of their cardiovascular risk factors would result in a tangible benefit in terms of reducing morbidity and mortality. Despite this, a number of scientific studies show that PAD is poorly managed even after diagnosis:

- The PREPARED (Prospective Registry and Evaluation of Peripheral Arterial Risks, Events and Distribution) study found that about one third of patients do not receive appropriate antiplatelet treatment.<sup>6</sup>
- Bradley and Kirker performed a retrospective review of referral documentation to a tertiary centre over the period 2004-2005, reviewing the 109 patients having an amputation for PAD.<sup>7</sup> Only 47% of these patients had been prescribed a statin by the time of referral to the prosthetic clinic and 60% were on an antiplatelet agent or warfarin. Only 39% of patients were on both a statin and an antiplatelet agent or warfarin and, worryingly, 32% were on neither – a cause for real concern given the incremental increase in disability likely to follow loss of a second limb.
- The AGATHA (A Global ATHerothrombosis Assessment) study in patients with or at risk of vascular disease also found evidence of sub-optimal management with only two thirds of dyslipidaemic patients receiving lipid-lowering therapy. In patients with vascular disease, use of lipid lowering agents was 48.7% and use of antiplatelets was 80.7%.<sup>8</sup>
- Cassar, Belch and Brittenden showed that optimum management would be prescribed by vascular surgeons for their patients in circa 50-60% of cases.<sup>9</sup>
- The poor management of PAD can have devastating effects on the patient's health, quality of life, and financial situation. It creates a considerable resource burden on the health service, and has a significant detrimental effect on the economy and society as a whole. The following chapters outline the effects of sub-optimal treatment of PAD on patients, the NHS, and the UK economy and society as a whole.

# Peripheral Arterial Disease (PAD)

## Primary Care Algorithm

Supported by an educational grant from sanofi-aventis and Bristol-Myers Squibb



### 3. The effects of sub-optimal treatment on the PAD patient

The long term health effects of untreated PAD can be significant. In terms of the disease itself, failure to stop the progression of PAD leads to the increasing deterioration of the blood circulation and much more severe pain. This can leave a patient virtually housebound, and if further restriction in blood flow occurs, wounds will have difficulty healing, leading to infections, permanent tissue damage and, in the worst cases, amputation. However, the health effects of untreated or poorly-treated PAD go much wider.

#### Health effects

Untreated PAD is heavily linked to other cardiovascular disease and events. The Joint British Societies' guidelines on prevention of cardiovascular disease in clinical practice state that "any symptomatic manifestation of atherosclerosis in any vascular territory puts a person at high risk of dying from cardiovascular disease."<sup>10</sup>

The Government's CHD National Service Framework acknowledged that cardiovascular disease accounts for about two thirds of all premature deaths in England, as well as major ill health in terms of physical and communication disability.<sup>11</sup>

One analysis estimates that symptomatic PAD carries a 30% risk of death within five years, rising to almost 50% within 10 years, mainly due to heart attack (60%) and stroke (12%). These risks are doubled in patients with severe disease requiring surgery.<sup>12</sup> Indeed, people with PAD are six times more likely to suffer a stroke or heart attack than those without the condition. Recent registries show that patients with PAD have a one-year cardiovascular event risk (that is, a risk of cardiovascular death, stroke, heart attack or hospitalisation) of 21.14%, which is significantly higher than that of CHD patients (15.2%).<sup>13</sup> Results also showed that event rates were higher in patients with polyvascular disease (that is, more than one of PAD, CHD and cerebrovascular disease) compared with those with known disease in just one vascular location. UK data extracted to date from these results show a very similar pattern of morbidity and mortality.

A recent analysis of data from the Framingham Heart Study<sup>14</sup> evaluated the impact of cardiovascular and cerebrovascular disease on life expectancy, based on data collected over 40 years from 5070 patients who did not have cardiovascular disease at entry to the study. The results of the analysis clearly demonstrate that atherosclerosis significantly reduces life expectancy. Healthy individuals aged 60 years were expected to live for a further 20 years (to the age of 80 years); however, a history of atherosclerotic events reduced life expectancy by between 9 and 16 years.

Caro *et al* reported similar findings in a Canadian study involving over 50,000 residents of Saskatchewan with previous heart attack (15,590), stroke (18,704) or PAD (16,440) followed-up between 1985 and 1995. Survival curve analysis demonstrated that life expectancy was reduced by approximately 7 years after a heart attack, 9 years after stroke and 6 to 7 years in patients with PAD. In addition, the already shortened life expectancy was further and substantially reduced in patients with more than one event; e.g., life expectancy was reduced by almost 16 years in patients with heart disease and stroke.<sup>15</sup>

Put simply, we believe that sub-optimal treatment and management of PAD ensures that a patient is far more likely to have a coronary event or stroke – often fatal – than if the disease is correctly managed. The patient is also far more susceptible to living with pain, and perhaps to needing amputation, with all of the knock-on health effects that this would entail.

#### Economic Impact on the Patient

As described above, one of the main outcomes of sub-optimal treatment experiences for patients diagnosed with PAD is severe activity-limiting pain or even amputation, both of which can lead to incapacity and disability.

It is well known that disabled people are less likely to be employed, and more likely to be economically inactive, than non-disabled people. Only half of all disabled people of working age are currently in employment, compared with 80% of non-disabled people of working age.<sup>16</sup> This of course has an impact on the economic wellbeing of individual PAD patients. The income of disabled people is, on average, less than half that of non-disabled people. Even after taking the equalising effects of the taxation and benefit system into account, disabled people still earn, on average, 30% less than non-disabled people. Furthermore, the additional costs of living with disability can be considerable.

This applies both to the costs of essential or highly desirable items of equipment (e.g., wheelchairs, assisted living products) and also to the cost of care, which may be undertaken by a family member or friend at significant opportunity cost to their own income.<sup>17</sup>

From extrapolating existing global data, we understand that approximately one fifth of PAD patients in the UK are aged below 65 years.<sup>18</sup> The REACH (Reduction of Atherothrombosis for Continued Health) registry tells us that 50% of patients who have a cardiovascular event do not work again.<sup>13</sup> Therefore, we estimate that there are over 27,000 PAD patients of working age in the UK who are unable to work full time because of their condition, and suffer from a consequent loss of income – the average full-time UK salary in 2006 was £23,244.<sup>19</sup>

Taking costs of care and living into account, Target PAD estimates that the economic cost to a PAD patient of sub-optimal treatment could run into many thousands of pounds a year, and could be considerably more for patients of working age.

## Quality of life effects

Across all cardiovascular disease areas, rigorous risk factor management undoubtedly results in improved quality of life. Studies show that this is clearly the case in PAD, and that most patients with symptomatic PAD suffer negative quality of life effects. Sleep and rest, emotional behaviour, mobility (including walking ability) and social interaction are all adversely affected by PAD.<sup>20,21</sup> Thus, it is not sufficient to manage cardiovascular risk alone, but the leg symptoms also need effective management.

Risk factor management can have an immediate, effect on patients' quality of life, and the long-term results of interventions improving cardiovascular outcomes can make a real difference. One study in this area concludes that without appropriate interventions, "affected individuals may be severely limited in their social and occupational activities."<sup>22</sup>

Effective diagnosis and treatment of PAD patients is vital in order to ensure that their quality of life is not adversely affected. The treatment pathway for PAD is outlined in the previous algorithm; lifestyle limiting symptoms can be managed by endovascular or surgical interventions (such as stenting). An analysis of the effects on quality of life of PAD among patients in Edinburgh concluded that "the considerable reduction in health-related quality of life in patients with claudication highlights the need for successful interventions to alleviate this condition."<sup>23</sup>

Guidelines published by the Scottish Intercollegiate Network (SIGN) on PAD state that "patients with claudication can have a significantly reduced quality of life due to their restricted mobility. Careful consideration needs to be given to drug and lifestyle management of claudication so that patients can achieve an optimum quality of life within the limitations of their condition."<sup>24</sup> Furthermore, effective management of PAD will have a positive impact on the quality of life of patients' families and carers – the economic effect of this impact is analysed below.



## 4. Effect on health services of sub-optimal management

As with so many aspects of health care, investment in correct diagnosis and treatment early in the PAD patient pathway can save a huge amount of resource further down the line.

This report has already explored the links between PAD and further cardiovascular events and this section will try to translate this link to illustrate the financial impact to the NHS of this disease.

Cardiovascular disease cost the NHS in the UK around £14,750 million in 2003. This represents a cost per capita of just under £250. The cost of hospital care for people who have cardiovascular disease accounted for about 76% of these costs, that of drugs and of dispensing them for about 18%.<sup>25</sup>

In PAD, this cost to the NHS can be best explained by the opportunity cost of a GP failing to correctly refer his or her PAD patients. If a GP sends a PAD patient for one outpatient appointment, the associated tariff cost would be £168.26 while an annual course of a statin, antihypertensive and antiplatelet therapy for an average patient would add £40.01 to this figure (based on the cost of treatment for one-year) – a total figure of £208.27. [Figures are based on one-year therapy of generic statin, generic ACE Inhibitor and generic antiplatelet.]

### Effect on NHS of worst-case scenario PAD-only procedure

As set out above, hundreds of PAD patients who have undergone sub-optimal treatment will require amputations. Set against the figure of £208.27 above, the tariff costs for amputation procedures are as follows:

- Amputations – £6,077
- Lower limb arterial surgery – £4,836
- Foot procedures for arterial disease, and procedures to amputation stumps – £2,019

Therefore the total cost for just the procedures themselves (not taking into account non-elective procedures, hospital stays, or further treatment) is £12,932 – over 20 times the cost of optimal average treatment. When multiplied up for the 100 plus PAD patients undergoing amputations every year, the total cost is more than £1.29 million.

### Effect on NHS of best-case scenario cardiovascular event

The one-year event rate for PAD is 21%, suggesting that just over one in five patients is likely to have a cardiovascular death, myocardial infarction (heart attack), stroke or hospitalisation in the space of a year.<sup>13</sup> Such an event is likely to cost well over the £208.27 for the well diagnosed and treated PAD patient as set out above:

- The tariff cost of an acute myocardial infarction without critical care is £2,089; with critical care, this is £4,527
- The tariff cost of non-transient stroke or cerebrovascular accident without critical care is £1,318 (for patients under 70 years); with critical care, the cost is £3,903

In the UK, 720,000 people have symptomatic PAD every year, and at least 22% of these will have an event each year (this is in fact a very low estimate based only on events occurring in the year following diagnosis – the real figure is likely to be much higher). Therefore, the costs to the NHS of just one non critical-care event for each of these patients would be at least £208 million per year on tariff costs alone.<sup>27</sup>

Referring to a number of clinical trials and other studies, Target PAD believes at least 23% of these events could be prevented with appropriate management of the condition. This means that, for just one small cohort of PAD patients who have a serious cardiovascular event up to one year after diagnosis, the NHS is spending around £47.84 million a year that it would not need to spend if the patients had received appropriate treatment earlier on in the treatment pathway.

## 5. Wider costs to society and UK plc

Of course, the economic effects of a sub-optimal treatment framework for PAD apply not just to the NHS, but to wider areas of Government spending and the UK economy as a whole.

### Wider costs

The wider costs to society of sub-optimal treatment can be measured in terms of

- Working days lost through illness and disability
- Working days lost through unpaid care of the ill or disabled
- Loss of taxation revenue to the exchequer
- Cost of benefit payments to ill and disabled

One recent study into the costs of coronary artery disease as a whole found that mortality from CHD in the UK cost £6.3 billion in 2001.<sup>28</sup> This study estimated that approximately 1.5 million working days, or £72.8 million, were lost due to hospitalisation for CHD in the UK in 2001. A further 6.3 million working days, or £297.8 million, were lost in time off work for recuperation following discharge from hospital. Costs to families incurred through visiting patients in hospital amounted to approximately £33.2 million in the UK in 2001.

There is some debate within the research community about the correct metrics for these costs. When adjusted for 'friction' – that is, the period of time it takes employers to find replacement workers, Shearer et al believe that the total 'indirect' (i.e., non-health) cost to society of CHD in 2001 was £702 million. Using different methodology, Liu et al estimated that in 1999 CHD cost the UK approximately £2.9 billion in productivity losses.<sup>29</sup>

Using REACH data, we can extrapolate the fact that an average of 128,524 PAD patients have a CHD event within one year (the 21% figure from the REACH study minus the 1.92% of the PAD population who have a non-fatal stroke<sup>19</sup>). Comparing this with the Shearer figures (880,690 patient CHD episodes), we can identify approximately 14.59% of the total CHD cost to society as being a direct result of one-year events from PAD patients – this amounts to £122.15 million using the Shearer methodology, or £531.44million using Liu's figures.<sup>30</sup>

There is no way of measuring the number of these events which could be prevented with optimal treatment; however, these figures do only represent the wider costs of events within one year. If this were extended to cover events over a number of years (clinical research pending), it is clear that the wider costs to society of this sub-optimal treatment of PAD would reach well over £100 million, and could exceed £500 million.

Moreover, there is a 'softer' cost to society of an unnecessarily incapacitated cohort of the population. This is expressed very clearly in the report of the Prime Minister's Strategy Unit on Improving the life chances of disabled people, which categorised the softer cost of incapacity as "fewer voices being expressed and taken into account in the democratic process and in the creation of the values and norms that shape society."<sup>16</sup> Put simply, poor treatment leads to more people being incapacitated, which has a negative impact on the general wellbeing of British society itself.

# 6. Conclusions and recommendations

This report has found that the sub-optimal treatment of patients diagnosed with PAD has a number of severe potential effects.

## Conclusions

Potential effects of sub-optimal treatment of PAD for patients:

- Greater risk of a serious or fatal cardiovascular event
- Greater risk of illness and incapacity
- Greater risk of financial costs relating to incapacity, which could reach many thousands of pounds a year
- A dramatic reduction in the patient's quality of life, and those of the patient's family/carers

Potential effects of sub-optimal treatment of PAD for the UK as a whole:

- Unnecessary costs to the NHS of at least £47 million pounds a year, based only on tariff payments for a small cohort of PAD patients – this could be better spent on prevention and appropriate treatment
- Unnecessary costs to the economy as a whole of between £100 million to £600 million per year, and corresponding negative effects on the wellbeing of society as a whole

Given these often catastrophic and expensive outcomes, it is clear that there is an urgent need to ensure better identification and treatment of people with PAD to reduce the burden of cardiovascular disease and help meet government targets.

**Target PAD recommends that action is taken to meet the need for appropriate and timely treatment to those diagnosed with the condition.**

We believe that there are three main practical steps which can be taken to achieve these goals:

### 1. Inclusion for PAD in the QOF

Currently PAD does not receive the same attention as the management of other cardiovascular diseases such as CHD and stroke. As part of their contract, GPs are awarded additional financial payments for undertaking a series of evidence-based interventions which are included in the Quality and Outcomes Framework (QOF) of the contract. Early evidence suggests that the QOF has been very successful in encouraging GPs to introduce these interventions.

Target PAD believes that GPs should be awarded QOF points if the practice could produce a register of people with PAD. This would encourage a renewed focus on the identification and appropriate management of patients with PAD. We are working with the GP contract negotiators to make the case for including PAD in the next QOF (currently being developed), and we have submitted detailed, evidence-based proposals in writing and in person to the QOF expert panel. We are confident that the benefits of including PAD in the QOF vastly outweigh the minor additional resource that this would entail.

As PAD has failed to be included within the QOF revisions in 2008, Target PAD would like to see the ankle brachial index, a simple test to diagnose PAD risk, alongside current cardiovascular indicators proposed for inclusion within the cardiovascular screening remit, whilst we continue to campaign for its inclusion in future QOF revisions.

## 2. Greater medical and public education

Target PAD is working hard to improve education and awareness of patients, health professionals and policy makers, resulting in PAD being given an appropriate proportion of health service resources and funding in both secondary and primary care. We are working to educate primary care as to the importance of diagnosis and treatment of PAD, and to educate patients regarding their condition through provision of an educational leaflet and other appropriate communications.

We believe that the NHS can do more to support this work by investing in medical and public awareness programmes around PAD – again, we believe that this investment will easily be returned by the long-term savings outlined above.

## 3. Appropriate prescribing

Much of the ‘downside’ in sub-optimal treatment of PAD comes from inconsistent or poor prescribing of NICE and SIGN approved treatments. Were national guidelines on the treatment of PAD to be properly implemented nationwide, a vast amount of cardiovascular events or PAD deterioration would be prevented, leading to a dramatic reduction in the negative health, economic and social effects described in this report. We would urge NICE, SIGN and the Department of Health to ensure that appropriate treatments for PAD are prescribed nationwide according to existing guidance.



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